BEFORE THE APPEAL COMMITTEE OF THE COUNCIL FOR MEDICAL SCHEMES HELD VIA THE MICROSOFT TEAMS VIDEO AND AUDIO CONFERENCE TECHNOLOGY INSTITUTED IN TERMS OF MEDICAL SCHEMES ACT NO 131 OF 1998

CMS 95911

In the appeal between:

K

(***on behalf of his minor son***,

J

(***Duly represented by Mr H***) Appellant

and

KEYHEALTH MEDICAL SCHEME First Respondent

THE REGISTRAR OF MEDICAL SCHEMES Second Respondent

RULING

CORAM:

Dr. X. Ngobese, Dr. T. Mabeba, Dr. H. Mukhari, and Dr. S. Naidoo (Appeals Committee Members) AND Adv T. Maphike (Chairperson).

INTRODUCTION AND BACKGROUND

1. This appeal is brought in terms of Section 48(1)[1] of the Medical Schemes Act 131 of 1998 ("the Act/MSA") against the ruling of the Registrar of Medical Schemes, ("the Registrar"), dated 3 August 2026, wherein the Registrar upheld KeyHealth Medical Scheme's ("KeyHealth" or "the Scheme") refusal to unconditionally fund the biologic medication Ravulizumab (Ultomiris) for a 15-year-old minor beneficiary, J, ("J"").

***J's Medical Condition*:**

2. J was diagnosed in July 2022 with Paroxysmal Nocturnal Hemoglobinuria (PNH; ICD-10 D59.5), a rare, acquired clonal stem cell disorder characterized by severe intravascular hemolysis. His treating clinical haematologist, Prof. M (Head of Clinical Haematology at the University of the Free State / Universitas Academic Hospital), prescribed Ravulizumab (Ultomiris), a long-acting C5 complement inhibitor.

***The Section 47 Complaints Process*:**

[1] Section 48(1) permits a person aggrieved by a decision relating to the settlement of a dispute or complaint in terms of section 47 to appeal to the Council

3. Following a failed complaints referral outcome under s 47,[2] on 3 August 2026, as alluded to, the Appellant lodged this statutory appeal under Section 48.

The Registrar's Findings:

4. Germane to the Registrar's dismissal of the Appellant's referral are its findings that:

> "*Ravulizumab does not form part of PMB level of care for treatment of the Dependant's condition. As such, the Respondent cannot be compelled to fund same in full, for the reasons stated above.*"

5. For the sake of completeness, the record would disclose that in its investigative functions in and for the Registrar's Office, the Clinical Review Committee (CRC) found as follows:

***The CRC's Findings*:**

6. **Are framed in the following terms:**

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[2] ***47.* Complaints.**
(**1)** The Registrar shall, where a written complaint in relation to any matter provided for in this Act has been lodged with the Council, finish the party complained against with full particulars of the complaint and request such party to furnish the Registrar with his or her written comments thereon within 30 days or such further period as the Registrar may allow.
(2) *The* Registrar shall, as soon as possible stir receipt of any comments furnished to him or her as contemplated in subsection (1), either resolve the matter or submit the complaint together with such comments, if any, to the Council, and the Council shall thereupon take all such steps as it may deem necessary to resolve the complaint.
(Issue

6.1 The CRC confirmed that ICD-10 code D59.5 (PNH) is a listed Prescribed Minimum Benefit (PMB),[3] falling under DTP 113S.

6.2 It recognized *Ravulizumab* as part of ongoing, evidence-based management of complement-mediated haemolytic PNH to reduce haemolysis and avoid transfusion dependency.

6.3 The CRC explicitly held that hospitalization does not provide or constitute a clinical or legal ground to withdraw, suspend, or re-assess funding for ongoing PMB treatment.

6.4 It confirmed that *Ravulizumab*'s disease-modifying efficacy is therapeutically distinguishable from, and materially superior to, blood transfusion, the latter being supportive care rather than disease-modifying in its clinical effect; modifying

6.5 The CRC also emphasized the aspect of clinical continuity arising from the use of the remedy.

CMS Legal Unit's Opinion, solicited at the Appellant's Behest

7. The record would also disclose that the Appellant solicited an opinion from the CMS's Legal Unit on the issue before or subsequent to the Registrar's s 47 ruling. The Legal Unit analyzed the Scheme's statutory non-

[3] PMB statutory foundation rests on s 29(1) (0) of the MSA read with Regulation 7, (which defines PMBs as the diagnosis, treatment and care costs of the DTPs listed in Annexure A). and Regulation 8, (which requires medical schemes, subject to the applicable regulatory provisions, to pay in full the diagnosis, treatment and care costs of PMB conditions, without co – payments and deductables), as well as Annexure A to the Regulations promulgated under the MSA.

compliance and identified constitutional breaches under Section s 28(2) of the Constitution.[4] This Unit advised *inter alia*:

7.1 PMB entitlements attach to scheme membership status, not benefit options. Option upgrades violate s 29(1)(0) and Regulation 8(1) of the MSA, which governs the PMB framework;

7.2 50% caps breach the PMB requirement for funding in full;

7.3 Lock-in and claw backs violate s 30 of the MSA;

7.4 Hospitalization is an invalid trigger for funding withdrawal by the Scheme.

7.5 The Legal Unit concluded that the Scheme's conditions represent an unlawful barrier.

***KeyHealth's Posture*:**

8. **This consisted of the following:**

8.1 KeyHealth issued a letter on 23 June 2026 directed to the Appellant which stipulated conditions precedent attaching to access to the requested funding, required to be met by the Appellant.

8.2 The referred-to letter conveyed, inter alia, extending a restricted cover to 50% MST/SEP, contingent upon the Appellant upgrading from its Equilibrium Option to Platinum; lock-in and claw-back provisions, respectively, contingent upon J's hospitalization for whatsoever reason, in case of such eventuality arising.

8.3 The record would also discern that on 5 August 2026, the Appellant proposed a tender for the payment of 50% of the cost of this remedy through funding procured from a third party; KeyHealth declined this compromise proposal.

8.4 Based on the record, KeyHealth was seemingly vindicated by the Registrar's ruling for the reasons the latter gave to dismiss the Appellant's referral in the s 47 process.

[4] Constitution of the Republic of South Africa, 1996 provides: the best interests of a child must be treated as a primary and overriding consideration in every matter concerning that child.

8.5 It bears mention that pursuant to the Registrar's decision, KeyHealth was legally enjoined to comply with s 48(2) of the MSA,[5] whose effect is to stay the execution of the Registrar's ruling, pending the determination and finalization of the issue in this Appeals Committee, in terms of s 48 (2). Save to say, this mandatory statutory imperative was ignored by it.

THE APPELLANT'S HIGH COURT APPLICATION FOR INTERIM INTERDICTORY RELIEF:

9. Following upon the Registrar's Ruling, the Appellant applied for interdictory relief at the Gauteng Division of the High Court, Pretoria, under case number: 2026 – 193480, with a return date of 30 October 2026, to stay the Registrar's decision, pending the outcome of this appeal and/or the finalization of Part B of its High Court application, whichever comes first. The hearing of this appeal was expedited in contemplation of institutional comity. It is intended to be issued on or before 30 October 2026 for publication and filing with the Registrar of the aforementioned Court.

THE S 48 APPEAL INSTANT AND REPRESENTATION:

10. This appeal served before this Appeals Committee on 12 and 13 October 2026.

10.1 Mr H appeared for the Appellant;

10.2 Mr N of Lawtons Attorneys, accompanied by Ms M, Ms P, Dr E(Expert witness – did not testify in person), and Dr N for KeyHealth

10.3 Ms. B appeared for the Registrar.

THE APPELLANT'S SUBMISSIONS AND GROUNDS OF APPEAL

11. Mr H expressed disquiet at the Registrar's decision expounding that based on an objective clinical necessity prism, supportive blood transfusions are temporary stopgaps failing to arrest intravascular haemolysis, acute

[5] ***(2)*** the operation of any decision which is the subject of an appeal under subsection (1) shall be suspended pending the decision of the Council on such appeal.

kidney failure risks, or life-threatening thrombotic events. *Ravulizumab* (Ultomiris) is the sole disease-modifying C5 complement inhibitor prescribed by treating specialist Prof. J.

12. The Appellant asserted that Keyhealth's 23 June 2026 letter consisted in an illegality. This letter, already referred to supra, imposed onerous conditions the Appellant was required to comply with for access to funding for the level of care treatment relating to this biologic. Among others, the Appellant was required to upgrade from his Equilibrium Benefit Option to Platinum, paying a 50% co-payment, agreeing to a 2026/2027 lock-in, subjecting funding to claw backs, and forcing reassessment upon hospitalization. The Appellant declared that this offended s 29(1)(o) of the Act read with Regulation 8(1) promulgated under this Act.

13. The Appellant extended an interim compromise to KeyHealth by submitting a tender and reduction proposal to leverage a 50% co-funding commitment from Alexion Interest-Free Co-Funding (AICF), capping KeyHealth's net exposure at R3.089m in Year 1, without compromising its claim to 100% statutory funding. This offer, which was apparently declined by the Scheme at s 47 stage, was subsequently withdrawn by the Appellant.

GROUNDS OF APPEAL: -

14. **<u>The Appellant's appeal grounds rest on the following</u>:**

***Misinterpretation of the PMB framework*:**

14.1 The Appellant contends that the Registrar erred in treating Ravulizumab's absence from the public-sector Essential Medicines List (EML) as determinative of whether it constitutes PMB level of care for the minor's PNH. The Appellant submits that the enquiry required consideration of section 29(1)(o) of the Medical Schemes Act 131 of 1998, Regulation 8, the listed condition and the applicable clinical standard of care.

Inadequate assessment of the clinical evidence:

14.2 The Registrar failed to adequately evaluate the treating specialist's prescription and the evidence concerning *Ravulizumab*'s disease-modifying role, the limitations of supportive transfusions, and the risks associated with ongoing haemolysis and complications of PNH.

***Failure to engage with material CMS clinical and legal opinions*:**

14.3 The Appellant submits that the Registrar did not adequately address the material conclusions recorded by the CRC and CMS Legal Department. Although those opinions were not necessarily binding, the Appellant contends that their substance required reasoned consideration before contrary conclusions were reached.

***Benefit-option upgrade condition*:**

14.4 The Appellant contends that the Registrar erred in upholding, or failing adequately to scrutinize, KeyHealth's requirement that the member upgrade from Equilibrium to Platinum as a condition of accessing the disputed treatment. The issue was whether that condition impermissibly made access to qualifying PMB treatment dependent on the member's benefit option.

***Proposed 50% funding limitation*:**

14.5 The Appellant submits that the Registrar failed adequately to determine whether the proposed 50% funding limitation complied with Regulation 8 and the applicable PMB funding requirements, including whether a qualifying designated service provider (DSP) was available and whether the legal prerequisites for a co-payment had been established.

***Lock-in and clawback conditions*:**

14.6 The Appellant contends that the Registrar failed adequately to assess whether the proposed membership lock-in and clawback arrangements were consistent with section 30 of the Act, the applicable scheme rules and the statutory nature of qualifying PMB entitlements.

***Hospitalization-triggered reassessment*:**

14.7 The Appellant submits that the Registrar failed adequately to consider whether reassessment, suspension or withdrawal of funding upon hospitalization or breakthrough haemolysis was clinically rational and legally permissible, particularly where those events may indicate deterioration or complications rather than the absence of a continuing treatment need.

***Best interests of the minor*:**

14.8 The Appellant contends that the ruling did not adequately demonstrate that the best-interests principle in s 28(2) of the Constitution was considered in assessing the consequences for the 15-year-old minor of restricting access to the prescribed treatment. The Appellant accepts that this principle does not itself dispense with proof of the statutory PMB entitlement.

***Inadequate reasons and rational connection*:**

14.9 The Appellant submits that the ruling does not sufficiently explain the reasoning linking the applicable statutory provisions, the clinical evidence and the conclusions reached, particularly regarding the EML benchmark, the internal CMS opinions and the conditions attached to KeyHealth's proposed authorization.

***Relief sought*:**

14.10 The Appellant seeks that the appeal be upheld and the impugned findings in the Registrar's ruling dated 3 August 2026:

14.10.1 Be set aside;

14.10.2 That the dispute be determined afresh in accordance with section 48 of the Act, the applicable Regulations and the clinical evidence; and

14.10.3 That KeyHealth be directed to fund *Ravulizumab* to the extent that it is established to constitute treatment required for J's qualifying PMB condition, without imposing any condition inconsistent with the Act or Regulations,

14.10.4 In the alternative, the Appellant seeks such further determination or remittal as is competent.

KEYHEALTH's OBJECTION TO THE CMS LEGAL UNIT'S OPINION

Procedural Aspect

15. Before engaging in the substantive merits of this appeal, it is convenient to dispose of a procedural issue relating to the legal opinion sought by the Appellant from the CMS Legal Unit (Legal Unit), as set out earlier in this Ruling.

16. The Scheme asks the Committee to disregard the opinion furnished by the Legal Unit at the Appellant's instance, contending that it has no probative value because it was obtained *ex parte*.

17. The objection is not upheld to the extent that it seeks automatic exclusion solely on that basis. The fact that an opinion was solicited by one party does not, without more, render every legal proposition contained in it irrelevant. The opinion is, however, neither binding authority nor a determination of the dispute, and it cannot substitute the Committee's independent adjudication.

18. The Committee distinguished between legal propositions and factual assertions. Any legal propositions identified in the opinion were considered only insofar as they are independently supported by the applicable legislation, the Act, its regulations and binding precedent, *in casu*.

19. The opinion itself does not establish disputed facts.

20. To the extent that the opinion introduced new factual material or substantive arguments not previously ventilated, procedural fairness requires that the Scheme be afforded a reasonable opportunity to answer, before the Committee relies on that material to the Respondent's prejudice. If necessary, the Committee may invite focused supplementary submissions. This is, however, not necessary because, in this appeal, the Legal Unit's opinion did not introduce new factual material and/or substantive arguments.

21. Accordingly, the objection is dismissed insofar as it seeks wholesale exclusion of the opinion merely because it was obtained *ex parte* and has no probative value purportedly.

22. The opinion carries no presumptive or binding force. The Committee's determination rests on the record; the parties' properly ventilated submissions and the law independently applied by the Committee.

23. Thus, while the Committee took note of the Scheme's objection, the legal opinion played no role in this determination, subject to the procedural-fairness safeguards set out in paragraphs 13, 14 and 15.

24. In any event, the Scheme was given an opportunity to respond to the 9 conditions it raised in its letter of 23 June 2026, and an independent determination is made herein based on its submissions and arguments.

KEYHEALTH'S SUBSTANTIVE MERITS SUBMISSIONS:

25. The Scheme submits that the dispute is not whether PNH constitutes a PMB condition. The nub of the issue is whether, as by the Appellant, Ravulizumab (Ultomiris) constitutes PMB-level care which it is obliged to fund in full subject to Regulation 8.

26. It posits that this distinction is fundamental. The fact that a beneficiary suffers from a PMB condition does not, without more, establish that every medicine, treatment or intervention prescribed for that condition constitutes the prescribed level of care which a medical scheme is obliged to fund in full. The statutory enquiry extends to the scope and level of the treatment prescribed for the relevant condition.

27. The Scheme accepts that, if Ravulizumab is established to constitute PMB-level care and no lawful DSP or other regulatory mechanism permits lesser funding, the statutory funding consequences must follow. The Scheme's case is that the Appellant has not crossed that threshold: clinical appropriateness and preference do not, without more, establish that Ravulizumab forms part of the prescribed PMB treatment component.

28. In sync with the Registrar's findings, KeyHealth submits that Ravulizumab falls outside PMB level of care due to its absence from the public sector EML**.**

29. The Appellant led its expert witness, Prof J, a haematologist attached to the University of the Free State, Universitas Hospital. Keyhealth presented evidence from its expert witness, Dr L, attached to Chris Hani Baragwanath Hospital.

PMB JURISPRUDENTIAL FRAMEWORK: -

***The intersection of statutory obligations, clinical evidence and constitutional justice*:**

30. At this stage, it is apposite to distill the jurisprudential scheme of Prescribed Minimum Benefits (PMBs), which, as a matter of law, incorporates its interpretative scheme. *Second*, to set out J's diagnosis, prognosis and present condition.

31. This is so in view of the fact that the nub of the dispute *in casu*, implicates a PMB condition and corresponding level of care if any, and where legally permissible, J must be availed the relief sought.

32. The starting point is that the determination of a dispute concerning PMBs requires more than an isolated reading of a medical scheme's rules, a clinical protocol or a particular provision of the MSA.

33. It requires a principled reconciliation of the statutory and regulatory framework governing medical schemes; the clinical evidence relevant to the condition and treatment in question, the constitutional imperatives informing the interpretation of legislation, and the binding jurisprudence of the superior courts.

34. The Committee's task is neither to substitute its own clinical preferences for properly established medical evidence nor to permit a medical scheme's contractual rules, internal protocols or administrative practices to displace obligations imposed by law. Its function is to determine, on the evidence and applicable law, the extent of the scheme's legal obligation, whether that obligation has been discharged, and what relief is justified within the powers conferred upon the Committee.

THE STATUTORY AND REGULATORY FRAMEWORK

35. The MSA, its Regulations, the prescribed PMB condition and treatment framework, and the applicable scheme rules must be read together. The scheme rules govern the contractual relationship between the scheme and its members, but that relationship exists within a statutory regime that prescribes minimum obligations which cannot lawfully be reduced by inconsistent contractual provisions.

36. In particular, the Committee must distinguish between the identification of a condition as a PMB condition and the separate determination of what constitutes the legally required level of care for that condition.

37. Regulation 8, Annexure A and the applicable diagnostic treatment pairs ("DTPs") must be examined in their proper context. The inquiry must extend to the diagnosis; the treatment sought; the clinical circumstances of the beneficiary; the applicable treatment protocols and the legal criteria governing the funding obligation.

38. The Essential Medicines List ("EML"); applicable public-sector treatment protocols and Explanatory Note 2 may materially assist that inquiry. Their relevance, however, must be assessed according to their legal source, purpose, wording and relationship to the governing provisions.

39. They must not be treated as interchangeable instruments, nor may an interpretive aid be elevated into a binding exclusion or entitlement without a proper legal foundation.

EVALUATION OF EXPERT EVIDENCE WITHIN THE APPLICABLE AND JURISPRUDENTIAL FRAMEWORK: -

40. The clinical evidence must be evaluated for its relevance, reliability, evidential foundation, and application to the particular beneficiary.

41. The Committee must identify the material points of agreement and disagreement between the experts, consider the reasons supporting their respective opinions, and determine whether the evidence establishes that the treatment sought falls within the applicable PMB level of care.

42. A scheme's reliance on a treatment algorithm, formulary, clinical guideline or preferred treatment pathway is relevant, but it does not, without more, resolve the legal question.

43. The Committee must determine whether the cited instrument applies to the particular condition and circumstances; whether the proposed alternative is clinically appropriate; and whether the scheme has demonstrated compliance with the governing statutory and regulatory requirements.

44. Conversely, the seriousness of a condition; the potential consequences of withholding treatment; or an expert's preference for a particular intervention does not, by itself, establish an unrestricted statutory entitlement to every requested treatment.

45. The conclusion must follow from the applicable legal standard, properly evaluated clinical evidence and the facts of the case

CONSTITUTIONAL INTERPRETATION AND THE CULTURE OF JUSTIFICATION

46. The interpretive exercise is informed by the Constitution, particularly sections 27, 28(2), and 39(2), where applicable. Section 27 recognizes the right of access to healthcare services, while section 28(2) provides that

a child's best interests are of paramount importance in every matter concerning the child. Section 39(2) requires legislation to be interpreted in a manner that promotes the spirit, purport and objects of the Bill of Rights.

47. These provisions do not dispense with the need to establish the content of the statutory entitlement. They do, however, require the Committee to avoid an unduly narrow, formalistic or constitutionally indifferent interpretation where the governing text reasonably permits an interpretation consistent with the Bill of Rights.

48. The relevance and weight of a child's interests must be assessed in the circumstances of the particular dispute.

49. Where a child is the beneficiary, as *in casu*, the Committee must give the child's best interests appropriate and independent consideration, rather than treating those interests as merely incidental to the contractual disagreement between the adult member and the scheme.

50. Professor Etienne Mureinik's seminal article, "***A Bridge to Where? Introducing the Interim Bill of Rights***"[6]supplies valuable jurisprudential orientation. Its enduring insight is the movement from a culture of authority to a culture of justification: the legitimacy of public power depends not merely on who exercises it, but on whether its exercise can be justified by cogent reasons.

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[6] (1994) 10 SAJHR 31,

51. In the present context, that insight requires a demonstrable chain of reasoning connecting the evidence; the governing law; the conclusions reached; and the relief granted.

JUDICIAL PRECEDENT AND THE WEIGHT OF LEGAL AUTHORITY

52. The Committee must distinguish binding judicial authority from persuasive material. Applicable Constitutional Court and Supreme Court of Appeal judgments must be followed according to their ***ratio decidendi*** and the established rules of precedent. Relevant High Court judgments, prior CMS Appeal Committee rulings; Appeal Board decisions; clinical and academic commentary must be considered according to their respective legal status; relevance and persuasive force.

53. Prior CMS rulings may assist in promoting consistency and principled decision-making, but they cannot override legislation or binding superior court authority. Equally, a previous ruling should not be distinguished or departed from without identifying a legally material difference, a relevant development in the law or another cogent reason.

54. The Committee must engage with precedent substantively rather than by citation alone. It must identify the principle established, explain its application to the facts, and address any material authority that points towards a different conclusion.

55. Ultimately, the Committee's responsibility is to deliver a decision that is legally correct, rationally connected to the evidence, procedurally fair, and capable of practical implementation.

56. It must neither enlarge the PMB framework beyond what the law permits nor allow administrative practice, contractual formalism, or an unexamined clinical protocol to defeat an entitlement that the law confers.

57. The central question is therefore not simply whether the scheme acted in accordance with its rules, but whether its decision, properly tested against the MSA; the Regulations; the applicable PMB framework; the evidence; constitutional principles and binding precedent, is legally sustainable, and, if it is not, what lawful and effective remedy the Committee is empowered to grant.

58. The same holds true against the Registrar's decision, given that the Appellant has brought this appeal against the Registrar's decision.

APPLICABLE LAW, LEGAL STATUS AND PROPER WEIGHT TO BE ATTACHED

59. The applicable law is the following:

Constitution of the RSA, 1996

59.1 Sections 27, 28(2), 33 and 39(2) inform rights, administrative justice and interpretation respectively.

MSA and Regulations

58.2 Section 29(1)(o) and (p), Regulation 7 and 8, and Annexure A are central to determining PMB obligations.

Binding Constitutional Court and Supreme Court of Appeal Precedent:

59.3 Binding according to the ***ratio decidendi***, court hierarchy and material facts.

Explanatory Note 2

59.4 Its effect depends on its legal source and status. It may aid interpretation but should not automatically be treated as an independent legislative obligation or exclusion.

Essential Medicine List and clinical protocols (EML).

59.5 Evidence of treatment policy and clinical practice; their legal relevance depends on the applicable PMB provisions and circumstances.

CMS Appeal Committee rulings:

59.6 Assists in establishing clinical facts and treatment standards; weight depends on foundation, reasoning and relevance.

Academic commentary

59.7 Persuasive intellectual guidance, not binding law.

60. Having mapped the applicable PMB framework, the Committee turns to J's diagnosis, prognosis and present clinical context against which the relevant legal principles must be applied.

J's DIAGNOSIS, PROGNOSIS, AND CLINICAL CONDITION

61. J's clinical diagnosis and pathology consist of:

61.1 Flow cytometry confirmed a large PNH clone comprising approximately 63% to 84% of granulocytes and monocytes, with bone marrow trephine biopsy showing hypocellularity and marked erythroid hyperplasia, confirming hemolytic PNH rather than primary bone marrow failure.

Severe Hemolysis Markers:

61.2 He has suffered from relentless, worsening intravascular hemolysis, evidenced by lactate dehydrogenase (LDH) levels soaring past 3,000 to 4,000 IU/L (approx. 12 to 16 times normal limits), undetectable haptoglobin, and severe recurrent hemoglobinuria (dark, black urine) occurring multiple times weekly.

Hematological Collapse & Transfusion Dependency:

61.3 Hemoglobin levels have plummeted to critical nadirs as low as **5.7 g/dL** (reference range 14.0–18.5 g/dL), necessitating emergency hospital admissions and red blood cell transfusions (e.g., March 2026 emergency admission requiring 3 units of packed cells and IV iron).

61.4 The clinical intervals between acute crises have dangerously shortened from 143 days to 23 days and 13 days.

61.5 Untreated hemolytic PNH carries a median survival of only 10 to 15 years, with approximately 50% mortality driven primarily by catastrophic, unpredictable thrombotic events blood clots in cerebral, hepatic, or mesenteric vessels.

61.6 J experiences debilitating smooth muscle dystonia symptoms (severe abdominal pain and dysphagia, chronic fatigue, and cognitive concentration difficulties that severely disrupt schooling and normal adolescent development.

Therapeutic Necessity:

61.7 Complement inhibition with Ravulizumab completely halts intravascular hemolysis, normalizes LDH, eliminates transfusion dependency, prevents fatal thrombosis, and restores life expectancy to that of age-matched healthy peers.

61.8 Furthermore, Ravulizumab's 8-weekly dosing schedule, compared to bi-weekly alternatives like eculizumab, minimizes travel and schooling disruptions for J's rural family.

CORE ISSUES FOR DETERMINATION

62. The Appeals Committee must determine the core legality of the Scheme's funding refusal and option-upgrade conditions, guided specifically by the four foundational inquiries set out below:

Alternative Pathway & Constitutional Obligations

62.1 *Did the scheme provide an alternative pathway to keep J stable, prevent organ failure, and preserve life, even if it required a different clinical mechanism than Ravulizumab*?

62.2 Keyhealth argued that supportive care, to wit, blood transfusions; iron/folic acid supplementation and anticoagulation, constitutes the prevailing public hospital practice under Explanatory Note 2.

62.3 However, expert clinical evidence establishes that supportive care is palliative and rescue-oriented, utterly failing to halt the underlying complement- mediated destruction or mitigate the fatal risk of thrombosis.

62.4 Furthermore, J's clinical condition has progressively deteriorated on supportive care alone, and repeated iron infusions have caused severe physical side effects, eg, abdominal cramps.

62.5 Because supportive care fails to maintain stability or prevent organ failure, the Scheme's constitutional obligation to protect life and bodily integrity, founded on Section 27 and Section 28 of the Constitution, has not been met.

62.6 The Scheme cannot circumvent enshrined fundamental rights and statutory scrutiny under the guise of an ineffective "alternative pathway."

The clinical appropriateness of the proposed alternative and the lawfulness of the Scheme's funding decision:

63. *Did* KeyHealth *provide an alternative treatment pathway that is clinically justifiable, aligns with the* MSA *and* Regulations*, and honours broader constitutional principles?*

63.1 If a scheme provides a genuine, clinically validated, and legally compliant alternative pathway, the dispute assumes a different legal dimension.

63.2 However, *in casu*, KeyHealth did *not* provide a clinically justifiable alternative.

63.3 Instead, it offered partial funding (50%) tied to a coercive commercial package: a mandatory option upgrade to Platinum; settling savings deficits; upfront contribution payments; a two-year lock-in; clawbacks, and hospitalization review threats.

63.4 This arrangement violates Regulation 8 -payment in full, Regulation 10(6) - savings protection, and Section 28(2) of the Constitution - best interests of the child.

63.5 The applicable legal framework does not support the Scheme's position, because its proposed "pathway" is nothing more than an unlawful commercial barrier designed to deter PMB claims.

63.6 The proper legal enquiry shifts from the clinical acceptability of the alternative to the lawfulness of the Scheme's funding decision.

Approved Therapeutic Regimen & Regulation 15H Compliance:

64. *Did the scheme provide an alternative pathway utilizing a different, approved therapeutic regimen that is scientifically proven to treat the PMB condition?*

64.1 *The answer may be that Regulation 15H is no longer violated.* If KeyHealth maintained a scientifically proven disease-modifying alternative regimen on the Equilibrium option such as an approved formulary alternative with equivalent clinical efficacy, Regulation 15H managed care protocols would be respected.

64.2 However, KeyHealth offered *no* alternative disease-modifying regimen; it offered basic supportive care, transfusions, while withholding disease-modifying targeted therapy.

64.3 Crucially, under Regulation 15HC, where standard supportive care is ineffective or causes harm to a specific beneficiary, mandatory exceptions *must* be made without penalty.

64.4 Because supportive care has failed and caused harm, Regulation 15HC compels full funding of the appropriate substitution treatment Ravulizumab.

64.5 Regulation 15H is therefore actively violated by the Scheme's refusal.

Burden of Proof at Section 48 Proceedings

65. *Did KeyHealth prove that a particular pathway exists during the Section 48 Appeal Committee hearing*?

65.1 The Appeals Committee sits as an objective statutory adjudicator to ensure that medical schemes do not evade their mandatory PMB obligations.

65.2 KeyHealth failed to discharge the evidentiary and legal burden of proving that a valid, evidence-based, disease-modifying alternative pathway existed within its Equilibrium option rules. Instead,

65.3 KeyHealth relied on bureaucratic non-procurement in the public sector founded on Explanatory Note 2 and option-based exclusions.

65.4 The Appeals Committee rules that the Scheme is acting entirely outside the framework of the MSA and its regulations.

STATUTORY AND REGULATORY FRAMEWORK

66. The proper discharge of this Committee's adjudicative mandate requires that the determination of this appeal be firmly anchored in the following legal pillars, which collectively govern interpretive exercise, circumscribe the permissible scope of decision-making, and inform the ultimate disposal.

Section 29(1)(o) of the MSA:

66.1. This statutory framework is material to the determination of the issue. The legislative construct is of particular moment on the aspect of the Scheme's insistence that the Appellant upgrades from the Equilibrium benefit Option to Platinum, to purportedly to enjoy the reach for funding the corresponding level of care.

Medical Schemes Regulations:

Regulation 8(1):

66.2. Mandates that *any* benefit option offered by a medical scheme must cover the diagnosis, treatment, and care costs of a PMB condition ***in full, without co-payments or deductibles***.

Regulation 8(2):

66.3. Permits reduced funding *only* where a beneficiary voluntarily utilizes a non-Designated Service Provider (DSP). KeyHealth explicitly conceded that no DSP mechanism was invoked.

Regulation 10(6):

66.4. Strictly prohibits utilizing a member's medical savings account to pay for PMB costs.

Regulations 15H and 15H(c) :

66.5. Govern managed care protocols and evidence-based medicine, expressly imposing mandatory exceptions without penalty where a standard protocol or treatment is ineffective or causes/would cause harm to a beneficiary.

Regulations 15H & 15I (Managed Care & Exceptions Process):

66.6. Managed care protocols cannot act as an absolute bar to necessary treatment.

66.7. Regulation 15I explicitly mandates that managed care programs must provide a transparent appeal and exception mechanism where a non-formulary or non-protocol drug is clinically required because standard protocol treatments are ineffective, cause adverse effects, or are exhausted.

66.8. Under Regulations 15H and 15I, where standard protocol treatments have been exhausted or proven ineffective, the scheme is required to evaluate clinical exception requests on an individualized, evidence-based basis.

66.9. Refusing to approve *Ravulizumab* (Ultomiris) when no alternative PMB treatment exists, converts the scheme's managed PMB care and is unconscionable.

Utilization of savings

66.10 The argument regarding pooled member funds and sustainability, while important in non-PMB benefit design, cannot be used to erode the statutory guarantee of PMBs.

66.11 As confirmed in ***Genesis CC*** *supra*, statutory PMB obligations are non–negotiable minimum obligations established by the legislator to prevent public health system overburdening and protect members during catastrophic illness.

Annexure A & Explanatory Note 2: DTP 113S (Acquired Hemolytic Anemias).

66.12 Explanatory Note 2 directs that broad categories, "medical management" follow prevailing public hospital practice.

66.13 However, explanatory notes is subordinate legislation, cannot override the primary statutory mandate of Regulation 8(1) or penalize rare disease patients for state-sector budgetary/procurement lags.

Constitutional & Statutory Protections for Children:

66.14 Section 28(2) of the Constitution provides that "*a child's best interests are of paramount importance"; the same is echoed by* Section 9 of the Children's Act 38 of 2005.

Binding Judicial Precedent:

66.15 Principles established in ***Council for Medical Schemes v Genesis Medical Scheme***,[7] and ***KeyHealth Medical Scheme v Ngoepe N.O.*** dictate that statutory PMB obligations override scheme rules, and financial constraints or mere state non-procurement cannot override clear clinical necessity.

66.16 In ***Genesis Medical Scheme v Registrar of Medical Schemes and Another***,[8] The Constitutional Court authoritatively settled the relationship between statutory PMB requirements and internal scheme rules.

66.17 The apex Court affirmed that PMB obligations are statutory imperatives designed to protect members. Medical schemes cannot invoke restrictive scheme rules, internal benefit options, or financial conservation arguments to avoid their statutory duty under Regulation 8(1) to pay PMB treatment costs in full.

66.18 Where a conflict arises between a scheme rule /policy and the statutory PMB mandate, the statute prevails.

[7] ([2015] ZASCA 161)
[8] [2017] ZACC 29; 2017 (6) SA 1 (CC)

66.19 In ***Mrs. S v Discovery Health Medical Scheme & The Registrar for Medical Schemes***,[9] the Appeal Committee overturned the Registrar's dismissal decision and ordered full funding for specialized oncology intervention (HIPEC) in advanced cancer. This ruling affirms the legal principle that schemes cannot hide behind internal managed care protocols to deny life-prolonging care for PMB conditions when standard options are exhausted and cause/would cause impairment or death.

ANALYSIS AND FINDINGS

Absolute Nature of PMB Entitlement - Regulation 8

67 It is common cause that PNH under DTP 113S is a listed PMB condition. Once a condition is classified as a PMB, Regulation 8(1) imposes an absolute, non-negotiable statutory duty on the scheme to fund its diagnosis, treatment, and care in full.

68 KeyHealth's attempt to bifurcate "clinical effectiveness" from "statutory level of care" is legally untenable. The undisputed expert evidence of Prof. M and the CMS Clinical Review Committee confirms that Ravulizumab is the first line, clinically appropriate standard of care, and that supportive care has failed.

Triggering of Regulation 15HC Exceptions:

69 The record demonstrates overwhelming, unrebutted evidence that standard supportive care is ineffective and harmful to J, hemoglobin dropping to 5.7 g/dL, severe hemolytic crises with LDH > 4,000 IU/L, and debilitating physical side effects from rescue iron therapy.

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[9] **CMS 84934**

70 Consequently, the statutory threshold under Regulation 15HC is decisively met. KeyHealth is legally bound to provide the appropriate alternative treatment, Ravulizumab, without financial penalty, co-payments, or compulsory option upgrades.

The Contextual Fallacy of the Public Sector Benchmark: Explanatory Note 2

71 Here, KeyHealth places much stock on Explanatory Note 2, arguing that because complement inhibitors are not routinely provided in public state hospitals, they fall outside PMB scope. This is rejected for the following reasons:

Systemic Public Hospital Procurement Lags:

72 State Essential Medicine List (EML) updates lag severely behind modern clinical science and fail to cater to ultra-rare conditions like PNH, whose incidence is 1–2 per million of the population.

72.1 Prof Malherbe adduced unrebutted evidence attesting that the EML was last updated in 2010.

The peremptory force of statutory primacy:

72.2 Subordinate explanatory notes cannot defeat the primary consumer-protection objectives of the Act and Regulation 8.

72.3 Keyhealth's Dr N confirmed that the force of Explanatory Note 2 is persuasive; it cannot override clinical necessity where required in a specific case.

Constitutional Imperatives:

72.4 Denying life-saving treatment to a child on the sole basis that the resource-constrained public sector has not procured it, despite proven clinical necessity and available manufacturer co-funding (AICF covering 50%), violates s 28 of the Constitution.

72.5 In its introduction, with reference to the paramountcy of the protection of children's rights, in **Teddy Bear Clinic for Abused Children and Another v Minister of Justice and**

Constitutional Development and Another, [10] the Constitutional Court enunciated as follows:

"Children are precious members of our society and any law that affects them must have due regard to their vulnerability and their need for guidance. We have a duty to ensure that they receive the support and assistance that is necessary for their positive growth and development. Indeed, this Court has recognised that children merit special protection through legislation that guards and enforces their rights and liberties.[1] We must be careful, however, to ensure that, in attempting to guide and protect children, our interventions do not expose them to harsh circumstances which can only have adverse effects on their development."

Section 8(2) of the Constitution makes clear that the Bill of Rights binds juristic persons, *in casu*, such as medical schemes and their administrators, as follows:

8 Application

(2) A provision of the Bill of Rights binds a natural or a juristic person f, and to the extent that, it is applicable, taking into account the nature of the right and the nature of any duty imposed by the right.

FINANCIAL SUSTAINABILITY AND SOLVENCY

73 KeyHealth raised generalized concerns regarding scheme sustainability and affordability under Regulation 15H. However, KeyHealth's audited 2025 financial statements reveal a robust financial position, with a solvency ratio of 41.6%, comfortably above the statutory 25% minimum, and a net surplus of **R 249.1 million**.

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[10] (CCT 12/13) [2013] ZACC 35; 2013 (12) BCLR 1429 (CC); 2014 (2) SA 168 (CC); 2014 (1) SACR 327 (CC) (3 October 2013)

74 Furthermore, the patient assistance co-funding mechanism (AICF) covers 50% of the drug cost, reducing the net financial impact on the Scheme to an insignificant fraction of its reserves. Financial sustainability can never be invoked to justify denying a statutory PMB to a critically ill child.

CONCLUSION:

75 In summary, the determination of this appeal required a principled harmonization of constitutional and statutory imperatives, clinical evidence, and binding judicial precedent.

76 Medical schemes operate within a tightly regulated public-interest framework where contractual freedom and internal rules are strictly subordinate to the primary consumer-protection objectives of the MSA and its Regulations**.**

The Culture of Justification and Constitutional Imperatives

77 As Professor Etienne Mureinik famously observed,

78 **"**Our constitutional democracy marks a decisive shift from a culture of authority to a **culture of justification,** where the legitimacy of any decision hinges upon a ruling that must disclose a coherent process of legal reasoning, demonstrating how the applicable statutory and regulatory framework, read against the evidence on record, yields the findings and consequential determination.

79 In short, a reasoned progression from law, through evidence, to determination.

80 In this matter, KeyHealth failed to supply a legally defensible justification for withholding treatment. Guided by **sections 27 and 28(2) of the Constitution**, the Committee gave independent and paramount consideration to minor J's best interests, ensuring that systemic and administrative barriers did not override a child's fundamental right to life, bodily integrity, and access to healthcare.

Statutory Primacy and the Fallacy of Explanatory Note 2

81 The statutory architecture is clear: once a condition is classified as a PMB under DTP 113S, **Regulation 8(1)** imposes an absolute, non-negotiable obligation on the scheme to fund its diagnosis, treatment, and care in full.

82 The Scheme's attempt to rely on Explanatory Note 2 and public-sector treatment benchmarks is legally flawed.

83 Subordinate interpretive notes and resource constraints in the public health sector cannot be elevated into binding exclusions capable of defeating primary statutory entitlements or penalizing patients for state-sector procurement lags.

84 Furthermore, KeyHealth's robust financial solvency, a 41.6% solvency ratio and substantial net surpluses, confirms that financial sustainability cannot be invoked to justify denying life-saving care.

The Lack of a Lawful Pathway and the Peremptory

85 KeyHealth failed to discharge its evidentiary and legal burden of establishing a valid, evidence-based disease-modifying treatment pathway within the Equilibrium option. Instead, it offered a coercive

commercial package, demanding a mandatory option upgrade, settlement of savings deficits, and multi-year lock-ins—coupled with basic supportive care that expert evidence proved to be palliative, rescue-oriented, and ultimately harmful.

86 Because standard supportive care has failed and caused physical harm, the statutory threshold under **Regulation 15H(c)** is decisively met. Regulation 15H(c) commands that mandatory exceptions be made without financial penalty when a standard protocol is ineffective or harmful.

87 Consequently, the Scheme is legally bound to fund the clinically proven substitution therapy, ***Ravulizumab*** **(Ultomiris)**, in full.

Applicable Jurisprudence and Final Determination

88 Adhering strictly to the doctrine of precedent and the superior court jurisprudence established in matters such as *Genesis* and *Ngoepe*, *supra*, this Committee has ensured that administrative convenience and contractual formalism remain subordinate to the governing statutory framework and its binding prescriptions**.**

89 The Registrar's decision upholding the Scheme's refusal is legally unsustainable and must be corrected.

90 The Scheme's funding decision must be evaluated not only against the PMB framework, but the constitutional obligation to give paramount importance to the child's best interest.

91 For these reasons, the appeal is upheld, and the Registrar's decision of 3 August 2026 is set aside and substituted as set out with particularity herein below:

RULING

92 Accordingly, the following Ruling issues:

1. The appeal is upheld;
2. The decision of the Registrar dated 3 August 2026 is hereby set aside and substituted with the following ruling:

   "KeyHealth Medical Scheme is directed to authorize and fund Ravulizumab (Ultomiris) in full as a PMB under DTP 113S for the treatment level care of the minor beneficiary, J , without requiring an option upgrade, co-payments, deductibles, or the utilization of medical savings accounts"

3. This funding order shall take effect immediately, taking into account any applicable third-party patient assistance co-funding such as AICF as presented in the record.
4. It is emphasized that this determination is case–specific, being confined to the particular facts, circumstances and evidence pertaining to J. It must not as establishing a general rule of application, in respect of other cases.
5. Any subsequent matter raising similar issues must be independently assessed and adjudicated on its own merits, with due regard to its distinct factual matrix, the applicable law and evidence placed before this Tribunal.
6. Together with publication, this Ruling must also be served on the Registrar, High Court of South Africa, Gauteng Division, Pretoria.

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Adv T Maphike

Member: Appeals Committee

DR X NGOBESE, DR S NAIDOO, DR. H. MUKHARI

HEARD:12 & 13 OCTOBER 2026

DELIVERED: 29 OCTOBER 2026