QUELimmune®
Selective Cytopheretic Device for Pediatrics (SCD-PED)

Payer Reimbursement Guide

Inpatient Hospital Setting | ICD-10-PCS Codes Effective October 1, 2026

1. Product Overview

QUELIMMUNE® (Selective Cytopheretic Device – Pediatrics, SCD-PED) is a humanitarian use device approved by FDA under a Humanitarian Device Exemption (HDE). It is indicated for the treatment of pediatric patients (weight ≥ 10 kg and age ≤ 22 years) with acute kidney injury (AKI) due to sepsis or a septic condition who are on antibiotic therapy and requiring renal replacement therapy (RRT).

QUELIMMUNE is connected in-line to an existing extracorporeal CRRT circuit and selectively targets highly activated neutrophils and monocytes to modulate the hyperinflammatory response.

Important: This guide focuses on inpatient hospital reimbursement. Coverage, coding, and payment policies vary by payer. Providers should verify benefits and requirements with each payer.

2. Coding Summary

ICD-10-PCS Procedure Codes (Effective October 1, 2026)

CMS has assigned dedicated ICD-10-PCS codes for renal replacement therapy with selective cytopheresis. These codes are reported on the inpatient claim (UB-04 / 837I) to identify the use of QUELIMMUNE.

Code	Description
5A1D701	Performance of Urinary Filtration, Intermittent, less than 6 Hours Per Day, Selective Cytopheresis
5A1D801	Performance of Urinary Filtration, Prolonged Intermittent, 6–18 Hours Per Day, Selective Cytopheresis
5A1D901	Performance of Urinary Filtration, Continuous, Greater than 18 Hours Per Day, Selective Cytopheresis

Select the code that matches the documented duration of the RRT session during which QUELIMMUNE was used.

Diagnosis Coding (ICD-10-CM)

Report the most specific diagnosis codes supported by the medical record. Common related codes may include (examples only – code to documentation):

- N17. – Acute kidney failure
- A41. – Sepsis / septicemia (or other septic condition codes)
- R65.2– Severe sepsis
- Additional codes for underlying conditions, organ dysfunction, or status as appropriate

HCPCS / Product Codes

As of the date of this draft, QUELIMMUNE does not have a unique HCPCS Level II code. Device cost is typically included in the inpatient MS-DRG payment. Some commercial payers may request the UDI or product identifier on the claim for tracking or separate payment consideration. Confirm with each payer.

3. Reimbursement Pathways by Payer Type

Medicare Fee-for-Service (Inpatient Prospective Payment System – IPPS)

- Payment is determined by the MS-DRG assigned based on principal diagnosis, secondary diagnoses, procedures (including the new ICD-10-PCS codes), age, sex, and discharge status.
- The new PCS codes enable accurate identification of selective cytopheresis cases for data, quality, and potential future payment policy evaluation.
- No separate NTAP (New Technology Add-on Payment) is currently assigned to these codes as of this draft. Payment is through the standard MS-DRG.
- Children's hospitals and certain other facilities may have different payment methodologies (e.g., TEFRA).

Medicare Advantage & Medicaid

- Coverage and payment policies vary by plan and state.
- Prior authorization or medical necessity review may be required.
- Confirm coding, documentation, and any single-case agreement requirements with the specific plan.

Commercial / Private Payers

- Policies differ widely. Many follow Medicare coding conventions but may apply their own medical policies.
- Prior authorization is commonly required for high-cost or specialized therapies.
- Some payers may consider case rates, outlier payments, or separate device payments under certain contracts.
- Recommend early engagement with the payer's medical management or specialty pharmacy team when appropriate.

4. Key Documentation Elements

Accurate and complete documentation supports coding, medical necessity, and reimbursement:

- **Indication match:** Pediatric patient ≥10 kg with AKI due to sepsis/septic condition on antibiotics requiring RRT.
- **Patient Documentation:** Document the patient's clinical characteristics and rationale for therapy, including whether use is consistent with the FDA-approved indication
- **Device identification:** Explicit documentation that QUELIMMUNE® / SCD-PED was placed in the extracorporeal circuit.
- **Duration:** Start and stop times or total hours of therapy to support the correct duration character (7, 8, or 9).
- **Clinical course:** Rationale for use, response to therapy, and any related complications or outcomes.
- **HDE context:** Note that the device is authorized under HDE for this rare pediatric population.

5. Economic Value Context

Published economic analyses have evaluated the potential budget and clinical impact of QUELIMMUNE in the indicated pediatric population. Results from these models suggested:

- The possibility of reduced hospital length of stay
- Reduced mortality
- Cost offsets compared with standard care assumptions.

These findings are model-based estimates derived from specified datasets and assumptions and may not be generalizable to all patient populations, institutions, or payer environments. Results are sensitive to underlying clinical and economic assumptions. See referenced publications for methodology, assumptions, limitations, and full study findings.

https://www.tandfonline.com/doi/epdf/10.1080/13696998.2025.2550860?needAccess=true

These analyses are illustrative and do not guarantee individual case outcomes or payer payment amounts. Facilities should perform their own cost accounting

6. Practical Tips for Revenue Cycle Teams

1. Update coding software and charge masters with the new ICD-10-PCS codes before October 1, 2026.
2. Educate clinical documentation improvement (CDI) and coding staff on the new codes and required documentation elements.
3. For commercial and Medicaid cases, initiate prior authorization early when the clinical decision is made.
4. Include the appropriate PCS code(s) on the inpatient claim in Form Locators 74 (or electronic equivalent).
5. Monitor remittance advice for any denials related to coding or medical necessity and appeal with supporting documentation as needed.

7. Support & Resources

- CMS ICD-10 files: https://www.cms.gov/medicare/coding-billing/icd-10-codes
- SeaStar Medical commercial / reimbursement support: quelimmune@seastarmed.com
- Facility coding leadership and payer contracting teams

IMPORTANT DISCLAIMERS

This document is an educational draft provided for informational purposes only. It does not constitute coding, billing, legal, or reimbursement advice. Coverage, coding, and payment are the sole responsibility of the healthcare provider and are subject to change. Always verify current codes, guidelines, and payer-specific policies. SeaStar Medical makes no guarantees regarding reimbursement for any product or service. The use of the codes and information in this guide does not guarantee coverage or payment.

QUELIMMUNE® was approved by FDA under a Humanitarian Device Exemption based on safety and probable benefit. The effectiveness of this device for this use has not been demonstrated. Adverse reactions observed in clinical studies include hypotension, hypothermia, tachycardia, hyperglycemia, and thrombocytopenia. Additional risks may include blood loss or extracorporeal circuit complications. QUELIMMUNE® must be used with citrate anticoagulation.

QUELIMMUNE® is a registered trademark of SeaStar Medical.