



Precision Desensitization In The Imlifidase Era: A Systematic Review of Biomarkers, Risk Stratification Models, and Personalized Treatment Algorithms For Hla-Incompatible Kidney Transplantation

Aldy Ridho Pangestu^{1*}, Tanaya Ghinorawa¹

¹Urology Division, Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada/Dr. Sardjito Hospital, Yogyakarta, 55281, Indonesia

*Email correspondence: ridhopangestualdy@gmail.com

Track Record Article	Abstract
Revised: 02 August 2026 Accepted: 28 September 2026 Published: 30 September 2026 How to cite: Pangestu, A. R., & Ghinorawa, T. (2026). Precision Desensitization In The Imlifidase Era: A Systematic Review of Biomarkers, Risk Stratification Models, and Personalized Treatment Algorithms For Hla-Incompatible Kidney Transplantation. <i>Contagion: Scientific Periodical Journal of Public Health and Coastal Health</i>, 8(3), 742–756.	<i>Highly human leukocyte antigen (HLA)-sensitized kidney transplant candidates with positive crossmatch have limited access to transplantation, prolonged exposure to dialysis, and increased mortality. Imlifidase, an IgG-cleaving enzyme, can rapidly convert positive crossmatch to a negative crossmatch; however the roles of immunological biomarkers, risk stratification, and personalized treatment protocols remain insufficiently defined. The study systematically searched PubMed, Web of Science, and the Cochrane Library for clinical studies involving adult HLA-incompatible kidney transplant candidates or recipients treated with imlifidase. Studies reporting donor-specific antibodies (DSA) or calculated panel reactive antibody (cPRA) together with crossmatch conversion, antibody-mediated rejection (AMR), patient and graft survival, and safety outcomes were included. Results were synthesized descriptively because of substantial clinical and methodological heterogeneity. Four clinical studies of imlifidase-treated HLA-incompatible kidney transplant recipients and one narrative review on biomarker-based risk models and personalized algorithms met the eligibility criteria, although the narrative review was used solely to provide conceptual context. Across the clinical cohorts, sample sizes ranged from 19 to 41 recipients, all of whom were highly sensitized, with median or mean cPRA values ranging from 90–100%. Imlifidase converted a positive crossmatch to a negative crossmatch in 89.5–100% of recipients within 24 hours, with short- to mid-term patient survival rates of 87.5–100% and graft survival rates of 84–100%. Early AMR occurred in 22–39% of recipients and was consistently associated with DSA rebound emerging within 3–15 days after imlifidase administration. Current evidence indicates that imlifidase provides a viable desensitization strategy for highly sensitized, crossmatch-positive patients who otherwise have limited transplantation options; however, this benefit is tempered by a substantial burden of early AMR associated with DSA rebound. Reliance on small, nonrandomized cohorts and heterogeneous immunosuppressive and monitoring protocols limits the certainty of the available evidence, underscoring the need for prospective multicentre studies to validate composite biomarker-based risk models and personalized treatment algorithms in imlifidase-enabled HLA-incompatible kidney transplantation.</i> Keywords: <i>Imlifidase, Kidney Transplantation, HLA-Incompatible, Desensitization, Donor-Specific Antibodies.</i>

INTRODUCTION

Highly sensitized kidney transplant candidates face a restricted donor pool because pre-existing antibodies against human leukocyte antigens (HLA) can render donor organs incompatible and increase the risk of antibody-mediated rejection (AMR). Sensitization is commonly assessed using calculated panel-reactive antibody (cPRA), virtual PRA, or calculated reaction frequency, although definitions and reporting methods vary across transplant systems. Candidates with a cPRA of at least 80–85% are generally considered highly

sensitized, whereas a cPRA of 98% or higher indicates extreme sensitization. In the United States, approximately 11% of waitlisted candidates have cPRA exceeding 80%, and 5% have a cPRA of at least 98%. Although allocation priority programs, acceptable mismatch programmes, and kidney-paired donation have improved access to transplantation, compatible donor offers remain exceptionally rare for candidates with a cPRA greater than 99.9% (Chowdhry et al., 2024; De Weerd et al., 2024; Furian et al., 2024; Mamode et al., 2022).

Extended dialysis is associated with substantial health risks, whereas kidney transplantation generally improves both survival and quality of life. For candidates who are unlikely to receive a compatible donor kidney, desensitization may be justified after consideration of the risks and benefits of transplantation relative to continued dialysis. Established desensitization strategies typically involve plasma exchange or immunoadsorption combined with intravenous immunoglobulin, with anti-CD20 therapy used as an adjunct in selected cases. However, their variable efficacy and relatively slow onset of action may limit their utility, particularly when unexpected deceased-donor organs become available (Huang et al., 2022; Kjellman et al., 2021; Mamode et al., 2022; Noble et al., 2023; Vo et al., 2024).

Imlifidase rapidly cleaves IgG, transiently reducing antibody activity and potentially converting a positive crossmatch to a negative crossmatch. In the Highdes phase II trial, 89.5% of recipients achieved a negative crossmatch within 24 hours; six-month patient and graft survival rates were 100% and 88.9%, respectively (Jordan et al., 2021). Across a cohort of 39 recipients, three-year patient survival reached 90%, while death-censored graft survival reached 84% (Kjellman et al., 2021). However, donor-specific antibodies (DSAs) frequently rebound within two weeks of treatment, increasing the risk of early antibody-mediated rejection (AMR). This review examines crossmatch conversion, predictors of DSA rebound and AMR immunosuppressive strategies, monitoring approaches, and survival outcomes, while comparing imlifidase-enabled transplantation with conventional desensitization strategies and standard care.

METHODS

Highly sensitized kidney transplant candidates face restricted access to compatible organs because preformed anti-HLA antibodies reduce donor compatibility and increase the risk of antibody-mediated rejection (AMR). Sensitization is commonly assessed using calculated panel-reactive antibody (cPRA), virtual PRA, or calculated reaction frequency, with a cPRA of ≥ 80 –85% generally defining high sensitization and a cPRA of ≥ 98 % indicating extreme sensitization. Although allocation priority programs, acceptable-mismatch programs, and kidney-paired donation have improved access to transplantation, candidates with a cPRA exceeding 99.9% rarely receive suitable donor offers. Prolonged dialysis is associated with

substantial health risks, making desensitization a potential option when transplantation is otherwise unlikely. Conventional desensitization strategies include plasma exchange or immunoadsorption combined with intravenous immunoglobulin, with anti-CD20 therapy used in selected cases; however, outcomes and treatment protocols remain variable. Imlifidase rapidly cleaves IgG, enabling the conversion of positive crossmatches to negative crossmatches and facilitating transplantation. However, donor-specific antibodies (DSAs) frequently rebound within 1 – 2 weeks after treatment, increasing the risk of AMR. This review examines imlifidase-enabled transplantation, predictors of DSA rebound and AMR, immunosuppressive strategies, monitoring approaches, and comparative patient and graft outcomes relative to conventional desensitization and standard care.

RESULTS

The PRISMA 2020 flow diagram (Figure 1) summarizes identification, screening, eligibility assessment, and inclusion of the four clinical studies and one narrative review.

Figure 1. PRISMA 2020 flow diagram for identification, screening, eligibility assessment, and inclusion of studies in the primary synthesis

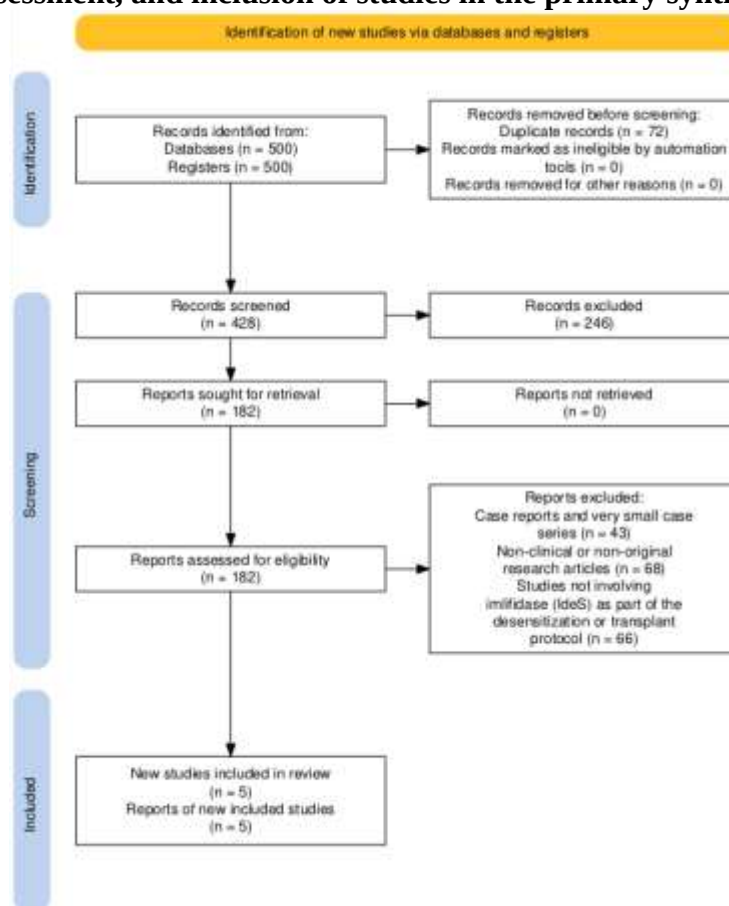


Table 1. Characteristics of included studies (n=4) plus one narrative review

Study	Design & Setting	Main population	Sensitization & donor characteristics	Imlifidase and co-treatments	Follow-up	Main clinical outcomes
Highdes phase 2 trial	Multicentre, single-arm, open-label phase 2 trial in adult kidney transplant recipients with positive crossmatch to the donor	Adults, highly HLA-sensitized, listed for kidney transplantation and showing positive crossmatch at baseline; all HLA-incompatible with their donor	Very high sensitization, median cPRA around 99.8; most grafts from deceased donors; high burden of DSA with one or more immunodominant DSA	Single course of imlifidase given before transplantation; additional regimen including lymphocyte-depleting induction, IVIg, rituximab, and standard maintenance (steroids, tacrolimus, mycophenolate)	6 months after transplantation	Within 24 hours, 89.5% achieved negative crossmatches; six-month patient/graft survival reached 100%/88.9%, despite 38.9% DSA-rebound-associated early AMR and acceptable eGFR
Pooled analyses of four phase 2 studies	Combined (pooled) analysis of four single-arm phase 2 trials of imlifidase in crossmatch-positive kidney transplant recipients	39 adult kidney transplant recipients with positive crossmatch who underwent imlifidase-enabled HLA-incompatible transplantation	Median cPRA around 99.6; all patients highly sensitized; majority received kidneys from deceased donors	Imlifidase used as part of pre-transplant desensitization (similar to Highdes), together with lymphocyte-depleting induction, IVIg, rituximab, and standard maintenance immunosuppression	3 years after transplantation	Successful crossmatch conversion enabled transplantation universally; three-year patient/death-censored-graft survival reached 90%/84%, eGFR 49–61, while one-third developed early DSA-rebound-associated AMR post-transplant
Five-year extension	Long-term (5-year) follow-up of the same	The same 39 recipients from the	Persistently characterized as highly	No new imlifidase courses; patients	5 years after transplantation	Five-year patient/graft survival reached

Study	Design & Setting	Main population	Sensitization & donor characteristics	Imlifidase and co-treatments	Follow-up	Main clinical outcomes
on cohort	phase 2 imlifidase-treated cohort	phase 2 cohort who previously received imlifidase and HLA-incompatible kidney transplants	sensitized; baseline cPRA and donor profile similar to the pooled analysis (mostly deceased donors)	followed under maintenance immunosuppression with serial monitoring of DSA and graft function		90%/82%, with eGFR of 50–56; DSA rebound declined, with no new AMR beyond year three observed
French multicentre real-world cohort	Multicentre observational cohort study from France, non-randomized	9 highly sensitized adult patients with positive flow cytometry crossmatch receiving kidneys from deceased donors	cPRA 99–100; all with extreme immunologic barrier and HLA incompatibility; all grafts from deceased donors	Single dose of imlifidase before transplantation; co-treatment with steroids, anti-thymocyte globulin, IVIg, rituximab, tacrolimus, and mycophenolate mofetil	About 7 months after transplantation	Imlifidase achieved 100% crossmatch conversion and patient/graft survival; eGFR averaged 56, while clinical/subclinical AMR affected 22.2% each amid frequent DSA rebound
Narrative review *	Narrative review of clinical literature on imlifidase in kidney transplantation and other IgG-mediated conditions	Not a primary patient cohort; synthesizes data from highly sensitized HLA-incompatible kidney transplant recipients and other antibody-me	Emphasizes features typical of highly sensitized patients, such as very high cPRA and substantial DSA burden, across multiple reports	No single intervention protocol; discusses various imlifidase regimens, timing issues relative to IgG-based therapies, and different immunosuppression combinations	No single follow-up duration; integrates short-, mid-, and long-term data from several studies	cPRA, DSA burden, MFI, dilution strength, and rebound guide personalized care, but validated risk models and standardized monitoring remain unavailable

Study	Design & Setting	Main population	Sensitization & donor characteristics	Imlifidase and co-treatments	Follow-up	Main clinical outcomes
		diated diseases				

*The narrative review is not a primary patient cohort and was used only to contextualize biomarker and risk-stratification concepts; it did not contribute independent quantitative outcome data to the synthesis.

As shown in Table 1, all included cohorts involved extremely highly sensitized adult candidates with HLA-incompatible donors and a positive crossmatch at baseline, positioning imlifidase as a gateway therapy in the highest-risk transplant population.

Table 2. Main synthesized outcomes from included studies

Outcome	Quantitative synthesized result (approximate)	Brief description
Baseline cPRA (sensitization)	Median/mean cPRA 90–100	All included cohorts involved extremely highly sensitized adults, typically with cPRA values in the upper range (about 90–100), indicating reactivity against most potential donors.
Crossmatch conversion rate	89.5–100% conversion from positive to negative within 24 hours	Across phase 2 and real-world cohorts, almost all imlifidase-treated recipients converted from positive to negative crossmatch; the lowest reported rate was about 89.5% and several cohorts achieved 100%.
Short-term patient survival (6–7 months)	100%	In early follow-up (Highdes phase 2 and French multicentre cohort), no patient deaths were reported, corresponding to 100% survival at approximately 6–7 months post-transplant.
Mid-term patient survival (3 years)	≈90%	Pooled analysis of phase 2 trials reported patient survival around 90% at 3 years, showing acceptable outcomes despite very high baseline immunologic risk.
Long-term patient survival (5 years)	87.5–90%	Extension data up to 5 years showed patient survival in the high-80s to about 90%, indicating durable benefit beyond the early post-transplant period.
Short-term graft survival (6–7 months)	88.9–100%	Early graft survival ranged from about 88.9% (Highdes) to 100% (French cohort), confirming that most imlifidase-enabled grafts remained functional in the first months.

Outcome	Quantitative synthesized result (approximate)	Brief description
Mid- to long-term graft survival (death-censored)	82–84% at 3–5 years	Death-censored graft survival in pooled phase 2 and 5-year extension cohorts was approximately 82–84%, indicating that the majority of grafts maintained function over several years.
Mean graft function (eGFR)	≈49–61 ml/min/1.73 m ²	Across studies, mean estimated GFR values generally fell between about 49 and 61 ml/min/1.73 m ² at mid- to long-term follow-up, suggesting moderate but clinically useful graft function.
Early AMR incidence	22–39% of recipients	Early antibody-mediated rejection occurred in roughly one-fifth to more than one-third of imlifidase-treated recipients, typically within the first 2–19 days or early weeks after transplantation.
Timing of DSA rebound	3–15 days after imlifidase	Rebound of donor-specific antibodies usually appeared between day 3 and day 15 post-implifidase, overlapping with the period when most early AMR episodes were observed.
Magnitude of DSA rebound	Often returning to ≈70–80% of baseline levels	In several reports, DSA levels rose back toward a large fraction of pre-treatment values after initial depletion, illustrating that the effect of imlifidase on IgG is rapid but transient.
Association between DSA rebound and AMR	Majority of AMR cases occurred in patients with documented DSA rebound	Studies consistently found that early AMR episodes were preceded or accompanied by DSA rebound, whereas patients without rebound rarely developed AMR, supporting a strong quantitative association.

**Note: Values in Table 2 represent approximate ranges across individual cohorts and are not pooled estimates. Given the limited number of nonrandomized studies and substantial heterogeneity in protocols, follow-up, and outcome definitions, formal meta-analysis and calculation of overall 95% confidence intervals were deemed inappropriate; thus only ranges and study-level descriptive statistics are reported.*

Table 2 summarizes the main synthesized outcomes: universal extreme sensitization (median/mean cPRA 90–100), rapid crossmatch conversion in approximately 89.5–100% of recipients, excellent short-term survival, acceptable mid- to long-term graft survival, moderate graft function, and an early AMR incidence of 22–39% closely linked to DSA rebound between days 3 and 15.

Table 3. Detailed JBI-based methodological appraisal of primary-synthesis studies

JBI domain (adapted)	Phase 2 trials (incl. Highdes)	Pooled 3-year analysis	5-year extension cohort	French multicentre real-world cohort	Brief description
Clear inclusion criteria	Yes	Yes	Yes	Yes	Studies enrolled highly sensitized, HLA-incompatible, crossmatch-positive adults, typically cPRA ≥ 90 –98%
Detailed description of participants and setting	Yes	Yes	Yes	Yes	Patient, sensitization, donor, and study-setting details clarify generalizability and context
Clarity and validity of exposure/intervention measurement	Yes	Yes	Yes	Yes	Imlifidase protocols detail dosing, timing, cotreatments, and standardized immunologic testing
Objectivity and validity of outcome measurement	Yes	Yes	Yes	Yes	Standard transplant measures ensured valid, reliable assessment of key outcomes.
Identification of confounding factors	Partial	Partial	Partial	Partial	Major confounders were recognized, but protocol heterogeneity prevented complete control
Strategies to deal with confounding	Limited	Limited	Limited	Limited	Uncontrolled trials and observational cohorts permit only

JB domain (adapted)	Phase 2 trials (incl. Highdes)	Pooled 3-year analysis	5-year extension cohort	French multicentre real-world cohort	Brief description
					descriptive confounding assessment
Completeness of follow-up	Yes (short-term)	Yes (3-year)	Yes (5-year)	Yes (≈7 months)	Defined follow-up intervals indicate high cohort retention and minimal attrition
Consistency of outcome measurement across participants	Yes	Yes	Yes	Yes	All participants underwent consistent outcome measurement, fulfilling JBI comparability requirements
Appropriateness of statistical analysis	Yes (descriptive ; single-arm)	Yes (pooled cohort analysis)	Yes (long-term cohort analysis)	Yes (observational cohort)	Descriptive and survival statistics appropriately match single- arm longitudinal study designs
Risk of bias due to study design	Moderate– high (no control group)	Moderate (analysis of existing non-randomized trials)	Moderate (long-term non-randomized follow-up)	Moderate– high (small observational sample)	Uncontrolled, small, heterogeneous studies heighten bias, motivating robust multicentre trials
Overall methodological appraisal (JBI-style)	Include, with caution	Include, with caution	Include, with caution	Include, with caution	JB deems evidence acceptable, but nonrandomized single-arm data limit comparative effectiveness inferences

Methodological quality was appraised using domains adapted from Joanna Briggs Institute (JBI) critical appraisal tools for clinical trials and observational cohort studies. All included studies clearly defined their eligibility criteria, provided detailed descriptions of participants and study settings, and used valid and reliable methods to measure exposures and outcomes. However, none incorporated randomized comparator groups, strategies to address potential confounding were limited, and observational cohorts were generally small. Overall, the evidence was considered suitable for inclusion but was subject to a moderate to high risk of bias, warranting cautious interpretation and limiting the generalizability of the findings to broader clinical practice.

DISCUSSION

This systematic review indicates that imlifidase can rapidly convert a positive crossmatch to a negative crossmatch, thereby enabling kidney transplantation in selected adults with extreme HLA sensitization and limited access to compatible donors. In the Highdes phase II study, 89.5% of recipients achieved crossmatch conversion within 24 hours. Similarly, a French real-world cohort reported conversion of all positive flow-cytometric and complement-dependent cytotoxicity crossmatch (Jordan et al., 2021; Kamar et al., 2024). Among 39 initially crossmatch-positive recipients followed for five years, patient survival was 90% and death-censored graft survival was 82% (Lorant et al., 2025).

The principal concern is early antibody-mediated rejection (AMR). In pooled phase II data, 38% of recipients developed AMR within six months, most commonly during the first month after transplantation (Lorant et al., 2025). Donor-specific antibodies (DSAs) rebounded between days 7 and 14 in five of nine recipients in a French cohort; all observed cases of early clinical or subclinical AMR occurred in patients who experienced DSA rebound (Kamar et al., 2024). Nevertheless, DSA rebound alone is not a reliable predictor of rejection because antibody measurements do not consistently reflect pathogenicity or the extent of graft injury (Rodriguez-Ramirez et al., 2022; Stel et al., 2024).

Comparison with alternatives

Unlike conventional desensitization strategies, imlifidase cleaves circulating IgG within hours, creating a transient window during which transplantation can proceed before antibody levels rebound. It may therefore benefit candidates with cPRA values approaching 100%, for whom compatible donor offers are exceptionally rare and repeated apheresis-based treatments may be ineffective or impractical (Kanbay et al., 2024; Mamode et al., 2022).

However, the available evidence is derived primarily from small, nonrandomized, , single-arm studies and therefore cannot establish superiority over alternative approaches, including conventional desensitization protocols, kidney-paired donation, or acceptable-mismatch allocation programs. Consequently, the use of imlifidase should remain selective rather than routine until more robust comparative evidence becomes available (Furian et al., 2024, 2025; Mamode et al., 2022).

Monitoring and personalization

Assessment should incorporate sensitization history, DSA burden and strength, crossmatch results, prior transplantation, repeated HLA mismatches, and changes in antibody levels following treatment. Higher pretreatment immunodominant DSA levels and repeated HLA mismatches may be associated with an increased risk of adverse outcomes; however, neither has been established as a validated clinical threshold for risk stratification (Kamar et al., 2024; Kjellman et al., 2021).

Post-transplant surveillance should integrate DSA monitoring with assessment of graft function and histopathological findings. Donor-derived cell-free DNA warrants further investigation as an additional biomarker of allograft injury, although the currently available diagnostic evidence has not been specifically validated in imlifidase-treated recipients (Akifova et al., 2024, 2025).

Clinical implications

Five-year mean eGFR in the pooled cohort was approximately 50–56 mL/min/1.73 m², suggesting meaningful function among surviving grafts (Kamar et al., 2024; Lorant et al., 2025).

Limitations and future research

Interpretation remains limited by small samples, heterogeneous protocols, and insufficient long-term biopsy data. Multicentre controlled studies should evaluate comparative outcomes and standardized monitoring; biomarker-guided care remains promising, not established.

CONCLUSION

Imlifidase-enabled desensitization substantially expands access to kidney transplantation for a small group of highly HLA-sensitized, crossmatch-positive candidates who would otherwise have few or no viable transplant options. Across four clinical studies, imlifidase consistently converted strongly positive crossmatches to negative in nearly all

treated recipients, while an additional narrative review highlighted the potential value of immunological biomarkers and risk-stratification frameworks.

However, this benefit is accompanied by a considerable risk of early immunological complications. Antibody-mediated rejection occurred in approximately one-fifth to more than one-third of recipients and was closely linked with rapid donor-specific antibody rebound within 3–15 days after treatment, underscoring that the profound IgG-depleting effect of imlifidase is transient and requires intensive peri-transplant immunosuppression and biomarker-guided monitoring. Given the current reliance on small, nonrandomized cohorts, heterogeneous concomitant treatment protocols, and the absence of validated composite biomarker-based risk scores, future prospective multi-centre studies should integrate detailed cPRA and DSA profiles into formal risk models and evaluate standardized immunosuppressive strategies and monitoring frameworks. Until such evidence becomes available, imlifidase should be regarded as a powerful gateway therapy for carefully selected, extremely high-risk candidates within multidisciplinary transplant programs capable of delivering protocolized, biomarker-driven desensitization and long-term follow-up.

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Data Availability

This review is based entirely on published aggregate data extracted from studies identified through systematic searches of PubMed, Web of Science, and the Cochrane Library, supplemented by targeted screening of transplant journals and backward citation tracking. The full search strategies, study selection log, and standardized data-extraction templates used in this review are available from the corresponding author upon reasonable request. No new individual-level clinical dataset was generated for this study.

Conflict of Interest

The authors declare that they have no conflicts of interest related to this work, including any financial or personal relationships with manufacturers or distributors of imlifidase or other desensitization therapies, or any other entities that could inappropriately influence the conduct, interpretation, or reporting of this systematic review.

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