Liposorber vs. Therapeutic Plasma Exchange

Category	Lipoprotein Apheresis (LIPOSORBER®)	Therapeutic Plasma Exchange (TPE)
Mechanism of Action	Selectively removes apoB-containing lipoproteins (LDL, Lp(a), VLDL) via targeted adsorption columns with limited removal of non-lipid plasma proteins. Thought to reduce lipotoxicity and inflammatory mediators.[1,2]	Non-selectively removes plasma constituents, including immuno-globulins, complement proteins, albumin, clotting factors, and protein-bound medications.[3]
Regulatory Status (FSGS)	FDA-authorized under a Humanitarian Device Exemption (HDE) for adult and pediatric patients with nephrotic syndrome associated with primary FSGS when standard therapy has failed or is not tolerated and GFR criteria are met, or following renal transplantation.	No FDA-approved indication specific to FSGS. Utilized per professional society guidelines.[3]
Representative Clinical Outcome*	~50% complete or partial remission in drug resistant and recurrent FSGS; higher response rates reported in small pediatric post-transplant case series.[4]	71% complete or partial remission in a systematic review of recurrent post-transplant FSGS treated with TPE.[5]
Adjunctive Drug Respon-siveness	May enhance responsiveness to corticosteroids and calcineurin inhibitors in some reports.[2]	Lack of evidence for drug responsiveness associated with treatment.
Treatment Course	Typically a short, structured treatment course (~9 weeks).	Often repeated or ongoing sessions
LDL-C / Lp(a) Reduction*	65-80% per session	~20-40%
Potential Adverse Events	Hypotension, light headedness, rare allergic reactions**	Volume shifts, infection risk, electrolyte imbalance

References:

1. Kaneka Medical America LLC.,2025 LIPOSORBER LA-15 Instructions for use in Focal Segmental Glomerulosclerosis (FSGS)
2. Raina R etal. Extracorporeal therapies in the treatment of FSGS. Blood Purification. 2020.
3. Connelly-Smith L, et al. Guidelines on the Use of Therapeutic Apheresis in Clinical Practice: The Ninth Special Issue. J Clin Apher. 2023;38(2):77–278.
4. Muso E etal. Long term effect of LDL apheresis on drug resistant nephrotic syndrome. Nephron Extra. 2015.
5. Kashgary A, et al. Plasma exchange in post-transplant focal segmental glomerulosclerosis: A systematic review and meta-analysis. BMC Nephrol. 2016;17:104.

* These data are derived from separate studies. There are no studies directly comparing clinical outcomes of LIPOSORBER to TPE for treatment of FSGS.

For LIPOSORBER safety information, visit: **liposorber.com/liposorber-safety-info

BMMKT0053

LIPOSORBER®

Provides Hope When Drug Therapy Fails™

FSGS Patient Identifier

Referral Guide

kaneka

liposorber.com

LIPOSORBER® Indications For Use: FSGS

The LIPOSORBER® LA-15 System is indicated for use in the treatment of adult and pediatric patients with nephrotic syndrome associated with primary FSGS when:

- Standard treatment options, including corticosteroids and/or calcineurin inhibitor treatments, are unsuccessful or not well tolerated, AND the patient's Glomerular Filtration Rate (GFR) is ≥ 60 ml/min/1.73 m^2
- OR the patient is post-renal transplantation.

Insurance Guidelines/Supporting Documentation

If clinical indications listed above are met, all diagnosis codes should be chosen by the referring/treating physicians along with:

- **Confirmed diagnosis of primary FSGS with nephrotic syndrome:** Diagnosis should be supported by kidney biopsy and clinical/laboratory findings consistent with nephrotic syndrome, including proteinuria, abnormal serum protein and lipid levels, and associated clinical signs.
- **Evidence of failure or intolerance to standard therapies:** Documentation should confirm failure, intolerance, or contraindication to maximally tolerated standard therapy, including corticosteroids and/or calcineurin inhibitors, consistent with current KDIGO recommendations.
- **Renal function (GFR) criteria:** Patient should have documented glomerular filtration rate (GFR) ≥ 60 mL/min/1.73m^2, consistent with FDA indication requirements for therapy.
- **Post-renal transplant status, if applicable:** Documentation may include recurrence of FSGS following kidney transplantation or clinical findings consistent with recurrent FSGS with nephrotic syndrome post-transplant.
- **Baseline proteinuria and kidney function assessment:** Baseline clinical measurements should be obtained prior to therapy initiation, including urinary protein levels and kidney function markers.
- **Patient eligibility criteria:** Documentation MUST include age ≥5 years, weight ≥ 21 kg, and supporting demographic and clinical eligibility information.

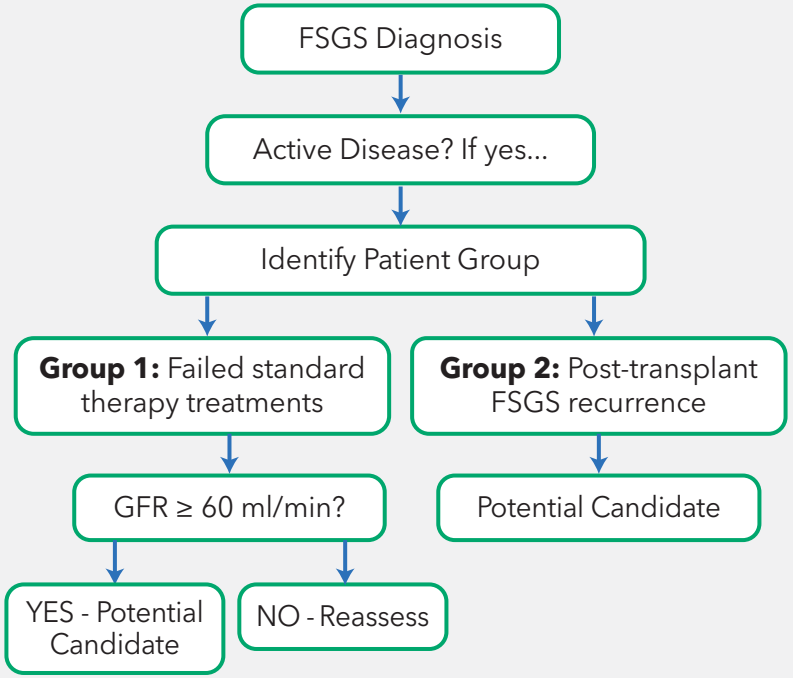
Reimbursement

LIPOSORBER is FDA-authorized under a Humanitarian Device Exemption (HDE), reimbursed through established hospital outpatient and Medicare pathways. To streamline implementation, Kaneka offers a dedicated reimbursement team—working directly with sites on coding, coverage, and operational setup to help ensure a smooth start and ongoing program success.

Referring your Patient for Treatment

- Discuss the expected treatment course, potential benefits, potential risks, current evidence supporting therapy, and appropriate patient expectations.
- Explain potential risks (i.e., hypotension, nausea/vomiting, flushing/blotching, etc.) and contraindication (the use of ACE inhibitors).
- Assure you have all required FDA documentation.
- Share patient education - brochures, patient assistance websites, treatment benefits, studies, etc.
- Send referral notes to treating provider/hospital.
- Support patient scheduling appointment with treatment center for a walk-through.
- Schedule follow-up visits to assure treatment outcome.

Referring Algorithm



LIPOSORBER Safety Information

For LIPOSORBER Indications for Use and safety information (contraindications, adverse events, etc.) please visit: **liposorber.com/liposorber-safety-info**