
Medical Policy



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***Current Policy Effective Date: 9/1/19**
(See policy history boxes for previous effective dates)

Title: Extracorporeal Liver Support Devices

Description / Background

Extracorporeal liver support devices are designed to carry out detoxification functions of the liver to support a patient in acute liver failure until the native liver has time to recover, or to bridge the patient to liver transplantation. This procedure is also referred to as liver dialysis.

Artificial support systems filter toxins in the blood, similarly to kidney dialysis, and use a sorbent-based system. Detoxification is provided without the use of cellular material. The Molecular Adsorbent Recirculating System (MARS™) was developed in Sweden and recycles an albumin solution and then dialyzes the albumin circuit. Single Pass Albumin Dialysis (SPAD) works similarly; however discards the albumin solution after a single passage of the membrane without being recycled. The Prometheus system was developed in Germany and is based on fractional plasma separation and adsorption. The method is combined with hemodialysis and does not include the use of exogenous albumin. In Selective Plasma Filtration Therapy (SEPET) the blood is filtered through a single-use cartridge that allows blood components with a molecular weight over 100kDa to be preserved, including albumin and clotting factors.²

Bioartificial support systems use cellular material and, in theory, provide many of the liver's synthetic functions in addition to detoxification. Hepatocytes from either human or porcine sources are integrated in cartridges used in the extracorporeal circuits, and may also include a sorbent. Bioartificial systems that use porcine hepatocytes and have been tested clinically include HepatAssist, the modular extracorporeal liver system (MELS), the Amsterdam Medical Centre bioartificial liver (AMC-BAL) and the bioartificial liver support system (BLSS).³The only Bioartificial system that uses human hepatocytes is the extracorporeal liver support device (ELAD™).

Regulatory Status

The artificial liver detoxification device: Molecular Adsorbents Recirculation System (MARS™) (Baxter International Inc., Deerfield, Illinois) is the only artificial liver detoxification system that has obtained 510(k) premarket approval for treatment of drug overdose, poisonings and hepatic encephalopathy (HE) due to decompensation of chronic liver disease.

At the present time, there are no bioartificial extracorporeal liver support devices with U.S. Food and Drug Administration (FDA) 510(k) premarket approval. There are several devices that are approved for use in clinical trials. One such device is ELAD® (Vital Therapies, San Diego, California) which uses cartridges containing human liver-derived cells, or VTL C3A cells.

Note: Mention of specific devices or systems in this policy does not represent an endorsement of a particular product. Brand names are used as examples of available devices/systems. It is not the intent of this policy to list all available or FDA approved products.

Medical Policy Statement

Use of extracorporeal liver support devices and all related services are experimental/investigational for all indications. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for the use of these devices.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT / HCPCS Level II Codes (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0405T

47399

Rationale

Extracorporeal liver assist devices are currently under study and may prove to be a useful option in the management of patients with liver failure in the future. Additional studies are needed to demonstrate safety, efficacy, clinical utility and improved health outcomes with the use of these devices.

The American Association for the Study of Liver Diseases (AASLD) Position Paper: The Management of Acute Liver Failure: Update 2011 states:

Recommendation 48. Currently available liver support systems are not recommended outside of clinical trials; their future in the management of acute liver failure remains unclear

In its 2011 Position Paper, AASLD reports:

“Few controlled trials have been published, and preliminary reports suggest no benefit to outcome, with or without transplantation... All such trials are difficult to perform and to control properly due to the rarity of well-characterized patients, the heterogeneity of etiologies, varying levels of disease severity, and varying access to liver transplantation.”

In September 2018, Vital Therapies reported that the ELAD® device failed to achieve primary and secondary outcomes in phase III clinical trials. The company announced it will not pursue further studies or development of the device.

Government Regulations

National:

There is no national coverage determination on this topic.

Local:

There is no local coverage determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Liver-Kidney (Combined) Transplant
- Liver Transplant
- Noninvasive Techniques for the Evaluation and Monitoring of Patients With Chronic Liver Disease
- Small Bowel /Liver and Multivisceral Transplant

References

1. Lee, W.M., Larson, A.M., Stravitz, R.T., “AASLD position paper: The management of acute liver failure: Update 2011.” Available at: https://www.aasld.org/sites/default/files/guideline_documents/alfenhanced.pdf (Accessed 4/9/19.)
2. Pless, G., “Artificial and bioartificial liver support”, *Organogenesis*, 2007, Vol. 3, No. 1, pp. 20-24.

3. Joseph NA, Kumar LK. Liver support devices: Bridge to transplant or recovery. *Indian J Respir Care* 2017;6:807-12. http://www.ijrconline.org/temp/IndianJRespirCare62807-4629593_125135.pdf Accessed 5/10/19.
4. Stutchfield, B.M., Simpson, K., Wigmore, S.J., "Systematic review and meta-analysis of survival following extracorporeal liver support," *Br J Surg*, 2011, Vol. 98, No. 5, pp. 623-31.
5. Thompson, J., Jones, N., Al-Kafaji, A., et al. "Extracorporeal cellular therapy (ELAD) in severe alcoholic hepatitis: A multinational, prospective, controlled, randomized trial," *Liver Transpl*. 2018 Mar, Vol. 24, No. 3, pp. 380–393.
6. Vital Therapies, Inc. Publications and Presentations: Clinical Experience with the ELAD System in Liver Failure.
7. Vital Therapies, News Releases: Vital Therapies Announces That Topline Results of VTL-308 Fail to Achieve Primary and Secondary Endpoints of Improvement in Survival, September 12, 2018. Retrieved from: <http://ir.vitaltherapies.com/news-releases/news-release-details/vital-therapies-announces-topline-results-vtl-308-fail-achieve> (Accessed 4/9/19).

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/9/19, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/16	6/21/16	6/21/16	Joint policy established
9/1/17	6/20/17	6/20/17	Routine maintenance
9/1/18	6/19/18	6/19/18	Routine maintenance
9/1/19	6/18/19		Routine maintenance Policy retired as obsolete

Next Review: This treatment has been determined to be obsolete and is no longer subject to routine review.

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: EXTRACORPOREAL LIVER SUPPORT DEVICES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Not covered
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.