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Policy Effective Date	**07/01/2024**
Policy End Date	**12/31/2025**

Removal of Ascites via Implantable Pump

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

The use of a subcutaneous peritoneal implantable pump system (e.g., alfapump®) in adults with refractory or recurrent ascites due to cirrhosis **is considered experimental, investigational and/or unproven**.

Policy Guidelines

None.

Description

Cirrhosis

Cirrhosis is a condition in which the liver is scarred and permanently damaged. Scar tissue will replace healthy tissue and prevent the liver from working normally; the scar tissue also partly blocks the blood flow through the liver. As cirrhosis worsens, the liver begins to fail. Many individuals do not have signs or symptoms and may be unaware they have cirrhosis until their liver is damaged. It is estimated that about 1 in 400 adults in the United States (U.S.) have cirrhosis. Cirrhosis is more common in individuals who have a history of heavy alcohol use, are overweight or obese, have type 2 diabetes, are male, and are 40 years old or older. (1)

As the liver begins to fail, complications may develop, including portal hypertension, which is when the scar tissue in the liver slows the normal flow of blood, causing high blood pressure in the portal vein (the large blood vessel that carries blood from the stomach, intestines, spleen, gallbladder, and pancreas to the liver). Once portal hypertension reaches a certain level, it can cause complications such as:

- Ascites: a build-up of fluid in the abdomen, which can lead to peritonitis, an infection in the space that surrounds the liver and intestines;
- Edema: swelling in the legs, ankles, or feet;
- Varices: enlarged veins in the esophagus, stomach, or intestines. These can lead to internal bleeding if the veins bursts;
- Hepatic encephalopathy: confusion or difficulty thinking caused by a buildup of toxins in the brain. (1)

There are no specific treatments that can cure cirrhosis and reverse liver damage. However, treating the causes may prevent cirrhosis or slow liver damage; and treating the complications may keep them from getting worse and prevent liver failure.

<u>Ascites</u>

In the U.S., ascites from cirrhosis accounts for approximately 80% of the cases. Individuals with cirrhotic ascites have a 3-year mortality rate of approximately 50%. Refractory ascites has a poor prognosis, with a 1-year survival rate of less than 50%. Up to 19% of patients with cirrhosis will have hemorrhagic ascites; this may develop spontaneously with 72% of the cases most likely due to bloody lymph fluid and 13% due to hepatocellular carcinoma. (2)

Symptoms of Ascites

Individuals may have progressive abdominal distention that may be painless or associated with abdominal discomfort, weight gain, feeling of fullness, shortness of breath, and dyspnea resulting from fluid accumulation and increased abdominal pressure. Small amounts of fluid in the abdomen usually cause no symptoms. Females have approximately 20 milliliters (mL) of intraperitoneal fluid depending on the phase of their menstrual cycle; males usually have little. Some individuals will have excess fluid accumulation in the ankles, causing edema. Symptoms such as fever, abdominal tenderness, and confusion can be seen in spontaneous bacterial peritonitis. (2)

Treatment of Ascites

Appropriate treatment of ascites depends on the cause of fluid retention. Goals of therapy are to reduce the ascitic fluid volume and decrease peripheral edema, without causing intravascular volume depletion. Sodium restriction and diuretics form the basis of treatment; and in cases of high-albumin-gradient ascites which occurs in cirrhosis, treatment includes abstinence from alcohol. (2)

Abdominal paracentesis is a procedure in which a needle is inserted into the peritoneal cavity and ascitic fluid is removed. Diagnostic paracentesis is the removal of a small amount of fluid for testing. Therapeutic paracentesis is the removal of more than 5 liters of ascitic fluid to reduce intra-abdominal pressure and relieve the associated dyspnea, abdominal pain, and early satiety. If the individual has refractory ascites, removal of as much fluid as possible will extend intervals between the procedures. (3) This may be referred to as large-volume paracentesis (LVP).

Transjugular intrahepatic portosystemic stent-shunt (TIPS, TIPSS) is a side-to-side portacaval shunt, usually placed through the right internal jugular vein. It reduces elevated portal pressure by creating a low-resistance channel between the hepatic vein and an intrahepatic branch of the portal vein using angiographic techniques. The tract is kept patent by deployment of an expandable stent across it, allowing blood to return to the system circulation. TIPS may be used for actively bleeding esophageal varices related to portal hypertension and refractory ascites. Complications associated with the procedure may include cardiac arrhythmias as the TIPS catheter is passed through the heart before accessing the portal vein, puncture of the liver capsule, portal vein rupture (rare, but potentially fatal), and injury to the biliary tree. (4)

alfapump®

The alfapump® (Sequana Medical, NV, Belgium) is a subcutaneously implantable, battery-powered pump system that automatically and continuously pumps ascites from the abdominal cavity into the bladder via tunnelled peritoneal and bladder catheters that are connected to the subcutaneous pump. The pump contains four pressure sensors to monitor the abdominal pressure and bladder pressure and to provide information on flow rate and system behavior. A pumping cycle is initiated only if the bladder pressure is below a certain threshold; at the same time, pumping is stopped when the pressure in the peritoneal cavity drops significantly indicating the pump cannot access sufficient fluid. (6) Individuals use a hand-held charging device that enables charging of the pump through the skin. While charging, data are transferred from the pump to the charge; and when placed on the docking station, the data are transferred wirelessly using the systems Directlink technology that allows physicians to monitor pump performance and more effectively manage their patients. The alfapump system is intended for use up to 2 years in individuals with refractory ascites due to liver cirrhosis or malignant ascites with a life expectancy of 6 months or less. It is not for use in individuals less than 18 years of age or those who may be pregnant. (5)

Regulatory Status

The alfapump® system is currently not approved by the United States (U.S.) Food and Drug Administration (FDA).

Rationale

This medical policy was developed in June 2024 and is based on literature searches using the PubMed database. The most current literature search is through June 4, 2024.

alfapump®

In a 2013 study by Bellot et al., they presented the results of a multicenter, non-randomized trial assessing the safety and efficacy of a new automated pump system for the treatment of refractory ascites (RA). (7) Forty patients at 9 centers (February 2010-June 2011) received an implanted pump for the automated removal of ascites from the peritoneal cavity into the bladder, from where it was eliminated through normal urination. Patients were followed for 6 months. The primary study outcome was safety. Secondary outcomes included recurrence of tense ascites and pump performance. Surgical complications occurred early in the study and became less frequent. The pump system removed 90% of the ascites and significantly reduced the median number of large volume paracentesis per month (3.4 [range 1-6] vs. 0.2 [range 0-4]; p <0.01). Cirrhosis-related adverse events decreased along follow-up. The authors concluded the automated pump seems an efficacious tool to move out ascites from the peritoneal cavity to the bladder. Its safety is still moderate, but a broad use in different countries will improve the surgical technique as well as the medical surveillance. A prospective randomized clinical trial vs. large volume paracentesis is underway to confirm these preliminary results.

In 2015, Thomas et al. described a single-center experience of ten consecutively implanted pump systems. Between August 2013 and November 2014, ten alfapump systems were implanted in patients with refractory ascites (RA) all suffering from liver cirrhosis. (8) Patients were treated as a bridge to transplant (4/10) or as an end-stage therapy (6/10). Median follow-up was 165 days (23-379 days). Postimplant, the need of paracentesis could be markedly reduced to a mean of 0.45 (0-4/month) per month. In eight patients, paracentesis was not needed after implantation of the pump system. The median daily output volume was 1000 ml/day (450-2000 ml/day). Prerenal insufficiency was a recurrent complication in the postoperative period. They concluded the system is useful in the treatment of patients suffering from therapy refractory ascites; however due to the high level of comorbidities, careful patient selection and postoperative monitoring are required.

A 2017 randomized controlled trial (RCT) in seven centers with a six-month patient observation was conducted by Bureau et al. (9) This study assessed safety and efficacy of an automated, low-flow pump (alfapump® [AP]) compared with large volume paracentesis (LVP) standard of care [SoC]. Primary outcome was time to first LVP. Secondary outcomes included paracentesis requirement, safety, health-related quality-of-life (HRQoL), and survival. Nutrition, hemodynamics, and renal injury biomarkers were assessed in a sub-study at three months. Sixty patients were randomized and 58 were analyzed (27 AP, 31 SoC, mean age 61.9 years, mean Model for End-Stage Liver Disease [MELD] 11.7). Eighteen patients were included in the sub-study. Compared with SoC, median time to first LVP was not reached after six months in

the AP group, meaning a significant reduction in LVP requirement for the AP patients (AP, median not reached); SoC, 15.0 days (HR 0.13; 95% CI 13.0-22.0; p<0.001), and AP patients also showed significantly improved Chronic Liver Disease Questionnaire (CLDQ) scores compared with SoC patients (p<0.05 between treatment arms). Improvements in nutritional parameters were observed for hand-grip strength (p=0.044) and body mass index (p<0.001) in the sub-study. Compared with SoC, more AP patients reported adverse events (AE) (AEs; 96.3% vs. 77.4%, p=0.057) and serious AEs (85.2 vs. 45.2%, p=0.002). AEs consisted predominantly of acute kidney injury in the immediate post-operative period, and re-intervention for pump related issues, and were treatable in most cases. Survival was similar in AP and SoC. The authors concluded the AP system is effective for reducing the need for paracentesis and improving quality of life in cirrhotic patients with RA. Although the frequency of serious AEs (and by inference hospitalizations) was significantly higher in the AP group, they were generally limited and did not impact survival.

Stirnimann et al. reported on the safety and efficacy of the use of a low-flow ascites pump in individuals with a contraindication to placement of a transjugular intrahepatic portosystemic shunt (TIPSS). (6) A total of 56 individuals (43 males, 13 females; mean age 62 years) were included and followed for up to 24 months. Complications, device deficiencies, paracentesis frequency, and patient survival were recorded. The median duration of ascites prior to implantation of the alfapump system was 11.0 months (8.0-19.0) with a median frequency of large volume paracenteses over the previous 3 months of 2.17 per month (1.45-4.34). At the time of the analysis, 3 patients completed the 24-month observation period, monitoring of 3 was ongoing, 9 underwent liver transplantation, 17 were withdrawn due to serious adverse events, and 23 patients died. The primary cause of deaths, during the study and after withdrawal, was progression of cirrhosis with decompensation. The most frequently observed technical complication was blocking of the peritoneal catheter by proteinaceous debris and/or fibrin clots and aspiration of the omentum (21 events in 13 patients). In 5 patients, the peritoneal catheter was either displaced, disconnected, or twisted. The bladder catheter was blocked or displaced in one case each. There were 2 procedure-related problems involving wound dehiscence. Twenty-three pump-related reinterventions (17 patients) and 12 pump exchanges (11 patients) were required during follow-up. The pump system was explanted in 48% of patients (in 17 patients due to serious adverse events, in 9 at the time of liver transplantation, and in 1 due to recovery from RA). Median frequency of paracentesis dropped from 2.17 to 0.17 per month. The authors reported the limitations of the study included the observational design without a direct comparison of the alfapump treatment with outer treatments that are considered as the current standard of care. The long-term management of the patients was left to the discretion of the treating physicians and did not follow a predefined protocol that was common in all treating centers, nor was there a requirement that all patients in each center be enrolled in the registry.

A 2018 study by Solbach et al. investigated the alfapump, an automated low-flow pump system for the treatment of RA as an alternative for repeated LVP in patients with a contraindication for placement of a transjugular intrahepatic portosystemic shunt (TIPS) or liver transplantation. (10) In 21 consecutive patients with RA and contraindication for a placement of a TIPS, the

alfapump was implanted between December 2012 and May 2016. Repeated laboratory, clinical, and microbiology data were collected and analyzed to assess the outcome of patients with an alfapump. Half of the patients received a modified peritoneal catheter. Twenty-one patients with RA in end-stage liver disease and with a contraindication to TIPS placement received the alfapump. Diuretic dosages were significantly reduced, and the number of paracenteses declined from 2.3±2.7 to 0 per week. Using the alfapump, kidney function and serum sodium remained stable. Likewise, serum albumin remained stable in the absence of albumin infusions. Thirty-three complications (dislocation and/or blockage of the catheter, infection, pump dysfunction) related to the alfapump were observed in 15 of 21 patients (71.4%), and 21 surgical interventions were needed in 15 patients (71.4%, 1-3 interventions per patient). A new peritoneal catheter system could significantly reduce blockage of the peritoneal catheter. The authors concluded the alfapump is an effective treatment in patients with RA. However, a high rate of complications were observed, which could be reduced with a modified peritoneal catheter.

Wong et al. (2020) reported on the Multicenter, Open-Label Study of the Alfapump System in Cirrhosis with Recurrent Ascites (MOSAIC) study, a prospective, open-label, feasibility study. (11) Following alfapump implantation, patients were monitored for ascites control, laboratory abnormalities, quality of life (QoL), adverse events, and survival at 12 months. A total of 30 patients (60.0 ± 9.9 years; 57% male; Model for End-Stage Liver Disease (MELD) score, 11.4 ± 2.7) received an alfapump, mostly by an interventional radiology approach (97%), followed by long-term prophylactic antibiotics. The alfapump removed a mean ascites volume of 230.6 ± 148.9 L/patient at 12 months, dramatically reducing the mean LVP frequency from 2.4 ± 1.4/patient/month before pump implantation to 0.2 ± 0.4/patient/month after pump implantation. All surviving patients had improved QoL (baseline versus 3 months; Chronic Liver Disease Questionnaire (CLDQ), 3.9 ± 1.21 versus 5.0 ± 1.0; Ascites Questionnaire (Ascites Q), 51.7 ± 21.9 versus 26.7 ± 18.6; P< 0.001 for both) and a better biochemical index of nutritional status (prealbumin 87.8 ± 37.5 versus 102.9 ± 45.3 mg/L at 3 months; P= 0.04). Bacterial infections (15 events in 13 patients), electrolyte abnormalities (11 events in 6 patients), and renal complications (11 events in 9 patients) were the most common severe adverse events. By 12 months, 4 patients died from complications of cirrhosis. Alfapump insertion may be a definitive treatment for refractory ascites in cirrhosis, especially in patients who are not TIPS candidates.

A retrospective study by Will et al. in 2020 reported the characteristics and outcomes of patients with cirrhosis receiving the alfapump or TIPS for RA at a single center. (12) In total, 19 patients with TIPS and 40 patients with alfapump were included. Patients with TIPS had better liver function and less hepatic encephalopathy at baseline. Fifty-eight percent of patients developed hepatic encephalopathy in the first six months after TIPS. In patients with alfapump, renal function decreased and 58% developed prerenal impairment and 43% hepatorenal syndrome in the first six months. Alfapump patients with new catheters required less reinterventions (26% versus 57% with old catheters, p = 0.049). Transplant-free survival at 1 year was 25% in alfapump and 65% in transjugular intrahepatic portosystemic shunt. Hepatic encephalopathy predicted transplant-free survival in patients with alfapump (hazard ratio 2.00,

95% confidence interval 0.99–4.02, p = 0.05). In a sensitivity analysis comparing patients with similar liver function, the rate of hepatorenal syndrome and prerenal impairment was higher in patients with alfapump and these patients were hospitalized more frequently, whereas the rate of hepatic encephalopathy was similar in both treatment groups. Both transjugular intrahepatic portosystemic shunt and alfapump were effective treatments for refractory ascites in cirrhosis. Patients treated with transjugular intrahepatic portosystemic shunt had a better one-year transplant-free survival but had less negative prognostic factors at baseline. Selecting patients without hepatic encephalopathy prior to implantation of an alfapump might improve transplant-free survival. This study has limitations related to the low number of cases, to the retrospective study design, to the different degree of liver failure of patients treated with TIPS versus those with alfapump and the indication bias. In addition, the strength of the evidence provided by such a study is much less than that afforded by a direct comparison of the two treatments through a trial. Therefore, these results should be interpreted with caution according to the authors.

Summary of Evidence

Several studies have evaluated the use of the alfapump® (Sequana Medical, NV, Belgium) in the treatment of refractory ascites as an alternative to repeated large-volume paracentesis or placement of a transjugular intrahepatic portosystemic shunt. The number of patients in the studies have been small and data is conflicting on the adverse events or complications reported. The alfapump has not yet received approval from the U.S. Food and Drug Administration. Therefore, the use of a subcutaneous peritoneal implantable pump system (e.g., alfapump®) in adults with refractory or recurrent ascites due to cirrhosis is considered experimental, investigational and/or unproven.

Ongoing and Unpublished Clinical Trials

Some currently ongoing clinical trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04326946[a]	International Alfapump Cohort Study: in Patients With Refractory Ascites Due to Liver Cirrhosis or Malignant Ascites With a Life Expectancy of 6 Months or Less	400	Dec 2025
NCT03973866[a]	Alfapump® System in the Treatment of Refractory or Recurrent Ascites: a Multicenter Single Arm Within Subject Crossover Design Pivotal Study (the POSEIDON Study)	110	Jun 2024

[a] Industry sponsored trial.

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0870T, 0871T, 0872T, 0873T, 0874T, 0875T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
07/01/2024	New medical document. The use of a subcutaneous peritoneal implantable pump system (e.g., alfapump®) in adults with refractory or recurrent ascites due to cirrhosis is considered experimental, investigational and/or unproven.