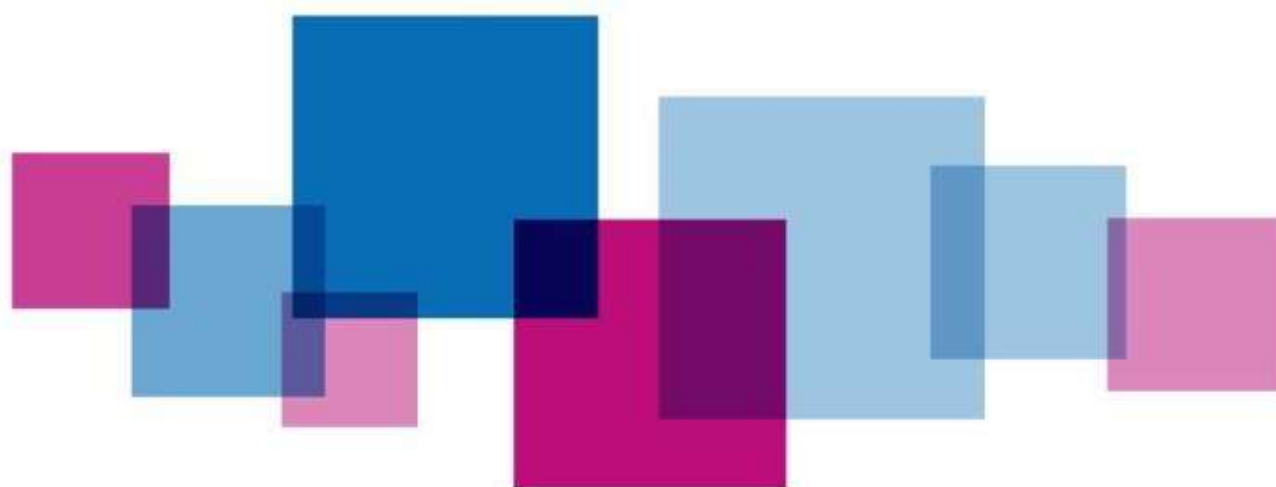


# Commissioning Policy

## Alfa Pumps for the Removal of Ascites due to Liver Disease

Prior Approval



**Date Adopted: 1<sup>st</sup> September 2019**

**Version: 1920.1.03**

## Document Control

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<b>Authors job title(s):</b>	Commissioning Policy Development Manager
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<b>Equality Impact Assessment Screening (date completed):</b>	May 2019
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<b>Patient and Public Involvement</b>	Alfa Pumps for the Removal of Ascites due to Liver Disease Policy

## Version control

Version	Date	Reviewer	Comment
V1617.1.01	26/03/2018	IFR Coordinator	Rebranded to BNSSG CCG
REVIEW	07/03/2019	CPD Manager	Rebranded to BNSSG CCG in preparation for 3 Year Review
REVIEW V1	23/05/2019	CPD Support Officer	Admin change
1920.01.02	03/06/2019	Commissioning Policy Development Manager	Admin changes in preparation for CPRG addition of OPCS codes
1920.01.03	20/06/2019	Commissioning Policy Development Manager	Post CPRG amendments
V1617.1.01	26/03/2018	IFR Coordinator	Rebranded to BNSSG CCG

**TREATMENT UNDER THIS POLICY REQUIRES PRIOR APPROVAL FROM THE ICB'S EXCEPTIONAL FUNDING TEAM**

**THIS POLICY RELATES TO ALL PATIENTS**

**Alfa Pumps for the Removal of Ascites due to Liver Disease is not routinely funded by the ICB and is subject to this restricted policy**

### General Principles

**Funding approval will only be given in line with these general principles. Where patients are unable to meet these principles in addition to the specific treatment criteria set out in this policy, funding approval will not be given.**

1. Funding approval must be secured by the patient's treating clinician prior to referring patients for surgical opinions. Referring patients to secondary care without funding approval having been secured not only incurs significant costs in out-patient appointments for patients that may not qualify for surgery, but inappropriately raises the patient's expectation of treatment.
2. On limited occasions, the ICB may approve funding for an assessment only in order to

confirm or obtain evidence demonstrating whether a patient meets the criteria for funding. In such cases, patients should be made aware that the assessment does not mean that they will be provided with surgery and surgery will only be provided where it can be demonstrated that the patient meets the criteria to access treatment in this policy.

3. Funding approval will only be given where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where it is demonstrated that patients have previously been provided with the treatment with limited or diminishing benefit, funding approval is unlikely to be agreed.
4. Patient with an elevated BMI of 30 or more may experience more post surgical complications including post surgical wound infection so should be encouraged to lose weight further prior to seeking surgery.  
<https://www.sciencedirect.com/science/article/pii/S1198743X15007193> (Thelwall, 2015)
5. Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing. (ASH, 2016)
6. In applying this policy, all clinicians and those involved in making decisions affecting patient care will pay due regard to the need to eliminate unlawful discrimination, harassment, victimisation, etc., and will advance equality of opportunity and foster good relations between people who share a protected characteristic and those who do not. In particular, due regard will be paid in relation to the following characteristics protected by the Equality Act 2010: age, disability, sex, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion or belief and sexual orientation.
7. Patients are required to abstain from alcohol in order to access this treatment. Funding will be withdrawn if the patient is found to have consumed any alcohol.

## Background / Purpose and Scope

### Alfa Pumps

When patients suffer from liver disease, the liver and kidneys stop working properly and fluid stops being exchanged within the cells in the way it should. This leads to ascites, an excess of fluid, which gathers in the abdomen. There is no way for this fluid to be removed from the body naturally and up to 15 litres of it can gather around patients' abdominal organs. Ascites can make patients look pregnant, as well as being painful, often causing hernias, and can take away the appetite, making patients weak and leading to malnutrition. These patients may have to make weekly trips to the hospital in order to have the fluid drained from their abdomen.

### The Alfa Pump system

The Alfa Pump, a CE-marked device, which is implanted beneath the skin of the abdomen, works by pumping fluid from the abdomen into the bladder, where it is removed from the body



naturally through urination. The fully implantable, battery powered, pump system eliminates the build-up of ascites and the onset of associated symptoms. In alcoholic cirrhotic patients once the symptoms of liver disease are reduced or eliminated, the liver has a better chance of recovery, as long as patients abstain from drinking alcohol. (McCune, 2015)

**Policy - Criteria to Access Treatment - PRIOR APPROVAL REQUIRED**

**The ICB will commission the use of the Alfa Pump system only when the following criteria have been met:**

The patient must have the ability to operate the device.

**AND**

The patient must have cirrhosis of the liver - defined by histological and/or clinical, and/or radiological criteria.

**AND**

The patient must present with refractory ascites\* and require periodic large volume paracentesis (large volume defined as  $\geq 5$  L in accordance with the clinical guidance of European Association for the Study of the Liver (EASL), which recommends withdrawal of 5 L should precipitate administration of albumin).

\*Definition of refractory ascites [Moore and Aithal, Gut 2006 Oct; 55 Suppl 6:vi1-12] Ascites that cannot be mobilised or early recurrence of which (that is, after therapeutic paracentesis) cannot be satisfactorily prevented by medical therapy.

This includes two different subgroups.

1. Diuretic resistant ascites - ascites that are refractory to dietary sodium restriction and intensive diuretic treatment (spironolactone 400 mg/day and frusemide 160 mg/day for at least one week, and a salt restricted diet of less than 90 mmol/day (5.2 g of salt)/day).
2. Diuretic intractable ascites - ascites that is refractory to therapy due to the development of diuretic induced complications that preclude the use of an effective diuretic dosage.

**Alfa Pumps will not be commissioned on ANY the following indications:**

- Patient has had a Gastrointestinal haemorrhage over the last 7 days
- OR
- Renal failure defined as serum creatinine higher than or equal to 2 mg/dl
- OR
- Severe coagulopathy defined as prothrombin time greater than 40% more than Upper Limit of Normal (as determined locally)
- OR
- Platelet count of less than 40,000 /  $\mu$ L unless platelet therapy is given at the time of surgery
- OR
- Clinical Evidence of recurring bacterial peritonitis, defined as 2 or more episodes over the last 6 months or a single episode within the last 2 weeks
- OR
- Clinical evidence of recurring urinary infections, defined as 2 or more episodes over the last 6 months or a single episode within the last 2 weeks
- OR
- Clinical evidence of loculated ascites
- OR
- Advanced hepatocarcinoma, defined as one which exceeds Milan criteria
- OR
- Obstructive uropathy, residual urinary volume exceeding 100ml, or any bladder anomaly which might contraindicate implantation of the device
- OR
- Other concomitant disease or condition likely to significantly decrease life expectancy or present anaesthetic risk (e.g., moderate to severe congestive heart failure)
- OR
- Immuno-modulatory treatment (including azothiaprime, methotrexate, anti-TNF therapies) used within last 4 months
- OR
- Known or suspected hepatic or extra hepatic malignancy, unless adequately treated or in complete remission for  $\geq$  3 years
- OR
- BMI>40 presenting a risk for surgery and tunnelled lines
- OR
- Patients with contraindications for general anaesthesia

(McCune, 2015)

For more information please see: <https://remedy.bnssgccg.nhs.uk/>

## Rationale for recommendation

In 2015 a New Interventions Group business case was submitted to the Clinical Policy Review Group (CPRG) outlining the benefits of the alfapump system as detailed below:

### **Significantly Reduces or Eliminates the Need for Large Volume Paracentesis**

The Pioneer Study (J. Hepatology 2013 vol. 58) demonstrated that the alfapump system was successfully implanted in all study patients and significantly reduces or eliminates the need for large volume paracentesis, therefore alfapump patients do not require repeated hospital visits for paracentesis, affording them a more normal life and reducing the burden on family or outside support. The pump system removed 90% of the ascites and at 6 months post implant significantly reduced the median number of large volume paracentesis per month [3.4 (range 1-6) vs.0.2 (range 0-4);  $p < 0.01$ ]

NCT01528410: A multicentre randomised controlled trial, including patients from Bristol, has completed recruitment and results are being analysed. The study is designed to evaluate the alfapump versus large volume paracentesis with primary outcome of paracentesis free survival at 6 months.

Results from a sub-study of the trial were published and presented at EASL April 2015 (Adebayo et al) and concluded that the alfapump is a safe and effective technology with improvement of nutritional parameters in patients treated with alfapump for refractory ascites. Results from a Post Market Surveillance Registry were also presented at EASL April 2015 (G. Stirnimann et al). From September 2012 data from patients with an alfapump have been collected in an international multicentre prospective registry.

In total, 55 patients were evaluated (76% men, 24% women), mean age was 61 (range 44–78). The median duration of the implantation was 60 min and the median length of hospital stay after implantation was 6 days (3/12). The number of large volume paracenteses per month decreased from 2.17 (1.4/4.3) to 0.0 (0.0/0.43), the volume of each paracentesis decreased from 7.0 litres (5.0/9.0) to 4.6 litres (3.0/6.0). The median volume of ascites pumped was 0.9 litres (0.7/1.1) per day.

The most frequent complication was obstruction of the peritoneal catheter in 11 patients, followed by pump failures due to technical problems in 7 patients and infections in 6 patients. Of 55 patients, 17 are ongoing, 18 died, 8 were transplanted, 10 were withdrawn, 1 completed the study and 1 was lost to follow-up. Mean survival was 6.33 +/- 5.33 months with a 6 month actuarial survival of 74%. Implantation of alfapump was found to be a safe procedure in patients with refractory ascites due to advanced cirrhosis and was associated with a marked reduction in the need for paracentesis and albumin.

### **Improves Patient Quality of Life**

As ascites collects in the abdominal cavity the coincident intra-abdominal pressure affects abdominal structures and organs and the associated discomfort can severely compromise patient quality of life. Patients often feel bloated, nauseous and fatigued. Lack of appetite



together with the strict sodium and fluid restricted diet that these patients must maintain to minimise ascites production leads to poor nutrition. In addition, significant energy expenditure is required to maintain large volumes of ascites at body temperature. Continual removal of ascites by the alfapump system results in a “flat belly” that enables patients to consume a more normal diet, thereby improving nutritional status. Patients feel better because they are no longer weighed down by large volumes of ascites and they become more mobile and active.

### **Reduces the Economic Burden of Refractory Ascites**

The NHS spends nearly £2bn every year on treating liver disease. Most recent figures show almost 50,000 people were admitted to hospital for alcohol-related liver disease in England, while 4,000 people in the UK die from the condition every year.

The alfapump system has the potential to deliver significant cost savings and efficiency improvements for healthcare providers. Paracentesis requires physician and nurse time and uses bed space that could be better used for other patients. In addition, there are real costs for the paracentesis kit, collection bags and human Albumin administered to avoid the risk of post paracentesis circulatory dysfunction. Recent literature shows that the cost of treating refractory ascites with paracentesis in the NHS exceeds £3,500 per month per patient. Following implantation of the alfapump system, this monthly cost is significantly diminished or eliminated entirely.

NHS National Innovation Centre supports the cost effectiveness of Sequana Medical's alfapump system, estimating the alfapump system has the potential to save the NHS between £50 and £100 million pounds in ascites care annually. Health Economics is being tested in the ongoing clinical studies- see also health economic evaluation below.

### **Bridge to Liver Transplantation**

Many physicians consider the alfapump system as a ‘bridge to transplant’ allowing for better management of patients awaiting transplant by minimizing the detrimental effects of large volume ascites and keeping the patient at home and out of the hospital as much as possible. Recent literature shows the more healthy a patient is prior to transplant the less costs there are to manage that patient after transplant.

The alfapump system does not affect a patient's eligibility for a liver transplant. To date, the Company reports that twelve patients have received a liver transplant after receiving the alfapump. This year transplant surgeons began leaving the alfapump in place after liver transplant for a period of time to manage ascites that occurs post-transplant thereby reducing the pressure on surgical wounds.

Liver centres have demonstrated that with some patients liver damage can be reversed and transplant can be avoided.

**<https://www.nice.org.uk/guidance/ipg631/documents/overview>**

Patients who are not eligible for treatment under this policy may be considered on an individual

basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy.

Individual cases will be reviewed at the ICB's Exceptional Funding Panel upon receipt of a completed application form from the patient's GP, Consultant or Clinician. Applications cannot be considered from patients personally.

## Due Regard

In carrying out their functions, the Bristol North Somerset and South Gloucestershire Commissioning Policy Review Group (CPRG) are committed to having due regard to the Public Sector Equality Duty (PSED). This applies to all the activities for which the ICB is responsible, including policy development and review.

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800 073 0907** or email them on [BSSSG.customerservice@nhs.net](mailto:BSSSG.customerservice@nhs.net).

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## Connected Policies

N/A

## This policy has been developed with the aid of the following references:

- Ash. (2016). *Ash.org.uk*. Retrieved Sept 24, 2018, from [www.ash.org.uk](http://www.ash.org.uk): [www.ash.org.uk/briefings](http://www.ash.org.uk/briefings)
- McCune, D. A. (2015). Alpha pump technology for the management of intractable ascites due to liver cirrhosis. *Bristol North Somerset South Gloucestershire New Intervention Group*.
- Thelwall, S. P. (2015). Impact of obesity on the risk of wound infection following surgery: results from a nationwide prospective multicentre cohort study in England. *Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases*, vol. 21, no. 11, p. 1008.e1.

## **OPCS Procedure codes**

Procedures challenged in this policy:

OPCS Code: T462

Relevant diagnoses for this policy:

ICD10 Code: R18X

Diagnoses for which the above procedures are permitted:

ICD10 Code: C22, C183, C221, C240, H500, H501, I500, K922, K658, K659, K650, N130, N131, N132, N133, N134, N135, N136, N137, N138, N139