PRESS RELEASE
NON-REGULATED INFORMATION
14 April 2025, 07:00 am CET

CMS Proposes Approval of Additional Payment for Sequana Medical's alfapump® system in Hospital Inpatient Cases

- ***New Technology Add-on Payment (NTAP) Included in Proposed Fiscal Year 2026 Rule, expected to be finalized in August 2025 and in effect by October 1, 2025***
- ***Launch centers on track to complete training by end of April***
- ***alfapump® US commercial launch remains on track for Q3 2025 through specialty commercial team focused on liver transplant centers***
- ***PMA approval received in December 2024, building upon FDA breakthrough designation in 2019***

Ghent, Belgium – 14 April 2025 – Sequana Medical NV (Euronext Brussels: SEQUA, the "Company" or "Sequana Medical"), a pioneer in the treatment of drug-resistant fluid overload in liver disease, heart failure and cancer, announced today that the Centers for Medicare and Medicaid Services (CMS) published the Fiscal Year 2026 Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule, which recommends that **alfa**pump system cases be eligible for incremental payment via a New Technology Add-On Payment (NTAP) from CMS when performed in the hospital inpatient setting. The annual proposed rule is now open for public comment and is expected to be finalized by August 2025 and in effect by October 1, 2025.

NTAP is a program designed to provide payment for qualifying new technologies in order to facilitate patient access to the new technology while CMS collects cost data. The NTAP program is intended to cover the majority of excess costs related to the new technology, though payment varies on a case-by-case basis. In its proposed ruling, CMS noted that the **alfa**pump system is an FDA-designated Breakthrough Device that meets the NTAP requirements and proposed the maximum allowable amount for an NTAP payment, which cannot exceed 65 percent of incremental device costs, or $19,500, in addition to the hospital's Medicare Severity Diagnosis Related Group (MS-DRG) payment.

The alfapump system is approved by the US FDA for the treatment of recurrent or refractory ascites due to liver cirrhosis. PMA approval was received in December 2024, building upon the FDA breakthrough designation received in 2019. It is the first active implantable medical device in the US that automatically and continuously removes ascites from the abdomen into the bladder, where it is naturally eliminated through urination. To date, over 1,000 alfapump systems have been implanted.

Martijn Blom, Chief Commercial Officer of Sequana Medical NV, commented: *"We applaud CMS for proposing an NTAP for the **alfa**pump system and for their commitment to improving Medicare beneficiary access to breakthrough technologies. This is another step forward in our US comercial launch and making this breakthrough therapy available to the large and growing US universe of patients that for too long have had to put with large volume paracentesis, a treatment that is virtually unchanged for thousands of years and has such a devastating impact on the clinical outcomes and quality of life for these patients. The team is highly motivated by the very positive feedback we are receiving from physicians who are looking for a 21st century treatment option for their patients and look forward to the launch in Q3"*

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About alfapump in recurrent or refractory ascites due to liver cirrhosis & the POSEIDON study
Recurrent or refractory ascites is a severe condition characterized by the accumulation of fluid in the abdomen. The current standard treatment involves therapeutic paracentesis, an invasive and burdensome procedure that drains ascites from the abdomen using a large needle over an extended period. The **alfa**pump is approved by the US FDA for the treatment of recurrent or refractory ascites due to liver cirrhosis. It is the first active implantable medical device in the US that automatically and continuously removes ascites from the abdomen into the bladder, where it is naturally eliminated through urination. To date, over 1,000 **alfa**pump systems have been implanted.

The US market of recurrent and refractory ascites due to liver cirrhosis is forecast to grow by an average of 9% per year, from approximately 70,000 patients in 2025 to 130,000 patients by 2032, primarily driven by the increasing prevalence of NASH / MASH[1]. The total market opportunity for **alfa**pump is estimated at over $2 billion in 2025, and is forecast to reach over $5 billion by 2035.

The FDA's approval of the PMA is based on the successful execution of Sequana Medical's pivotal POSEIDON study, a landmark study across 18 centers in the US and Canada with a total of 69 patients implanted with the **alfa**pump. The primary effectiveness endpoints at six months post-implantation in the Pivotal Cohort[2] exceeded the predefined thresholds with statistical significance, and primary safety endpoint data was in line with expectations[3]. Data at 12 months post-implantation continued to show a strong and durable clinical profile, virtually eliminating the need for therapeutic paracentesis and delivering an improvement in quality of life (as defined by subjective physical health (assessed by SF-36 PCS) and ascites symptoms (assessed by Ascites Q))[4]. At AASLD's The Liver Meeting in November 2024, key POSEIDON investigators reported that the **alfa**pump virtually eliminated the need for large volume paracentesis at 24 months, with overall survival of 62%[5].

The POSEIDON manuscript published in the American Journal of Gastroenterology in January 2025 concluded "the results from the literature indicate that the overall survival of patients with the **alfa**pump was not worse as compared to TIPS and was higher than reported for standard of care (LVP)[6]".

Data from the patient preference study and a matched cohort analysis of the NACSELD-III registry with the POSEIDON Pivotal Cohort indicated that US patients have a strong preference for the **alfa**pump vs standard paracentesis procedures and that the safety profile of the **alfa**pump is comparable to standard of care[7].

[1] Based on US and Canada market assessment conducted by highly experienced international consulting group
[2] The Pivotal Cohort is used for the primary effectiveness endpoints and consists of 40 patients implanted with the **alfa**pump
[3] Data reported in press release of 25 October 2022
[4] Data reported in press release of 19 October 2023
[5] Based upon the pivotal cohort of the POSEIDON study, data reported in press release of 18 November 2024
[6] The Effects of **alfa**pump on Ascites Control and Quality of Life in Patients with Cirrhosis and Recurrent or Refractory Ascites" A*merican Journal of Gastroenterology*
[7] Data reported in press release of 19 October 2023; Patient Preference study conducted by RTI Health Solutions, and matched cohort analysis presented by Dr. Bajaj at EASL Congress 2024.

About Sequana Medical

Sequana Medical NV is a pioneer in treating fluid overload, a serious and frequent clinical complication in patients with liver disease, heart failure and cancer. This causes major medical issues including increased mortality, repeated hospitalizations, severe pain, difficulty breathing and restricted mobility. Although diuretics are standard of care, they become ineffective, intolerable or exacerbate the problem in many patients. There are limited effective treatment options, resulting in poor clinical outcomes, high costs and a major impact on their quality of life. Sequana Medical is seeking to provide innovative treatment options for this large and growing "diuretic resistant" patient population. **alfa**pump® and DSR® are Sequana Medical's proprietary platforms that work with the body to treat diuretic-resistant fluid overload, and are intended to deliver major clinical and quality of life benefits for patients, while reducing costs for healthcare systems.

The Company received US FDA approval for the **alfa**pump System for the treatment of recurrent or refractory ascites due to liver cirrhosis in December 2024, following the grant of FDA Breakthrough Device Designation in 2019. Sequana Medical intends to start US commercialisation early in the second half of 2025 through a small specialty salesforce that it will establish to target the 90 US liver transplant centers that perform 95% of liver transplants.

Results of the Company's RED DESERT and SAHARA proof-of-concept studies in heart failure published in European Journal of Heart Failure in April 2024 support DSR's mechanism of action as breaking the vicious cycle of cardiorenal syndrome. All three patients from the non-randomized cohort of MOJAVE, a US randomized controlled multi-center Phase 1/2a clinical study, have been successfully treated with DSR, resulting in a dramatic improvement in diuretic response and virtual elimination of loop diuretic requirements[8].

Sequana Medical is listed on the regulated market of Euronext Brussels (Ticker: SEQUA.BR) and headquartered in Ghent, Belgium. For further information, please visit www.sequanamedical.com.

Important Safety Information: For important safety information regarding the **alfa**pump® system, see https://www.sequanamedical.com/wp-content/uploads/ISI.pdf.

The **alfa**pump® System is currently not approved in Canada.

DSR® therapy is still in development and is currently not approved in any country. The safety and effectiveness of DSR® therapy has not been established.

Note: **alfa**pump® and DSR® are registered trademarks.

Forward-looking statements

This press release may contain predictions, estimates or other information that might be considered forward-looking statements. Such forward-looking statements are not guarantees of future performance. These forward-looking statements represent the current judgment of Sequana Medical on what the future holds, and are subject to risks and uncertainties that could cause actual results to differ materially. Sequana Medical

[8] Data reported in press release of March 25, 2024; mean increase of 326% in six-hour urinary sodium excretion at 3 months follow up vs baseline, and 95% reduction of loop diuretics over same period

expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release, except if specifically required to do so by law or regulation. You should not place undue reliance on forward-looking statements, which reflect the opinions of Sequana Medical only as of the date of this press release.