PRESS RELEASE
September 28, 2023

DiviTum® TKa to pursue Gap-fill process for CMS pricing decision

Biovica, active in cancer monitoring, today announces that the Center for Medicare & Medicaid Services (CMS) has issued a preliminary CLFS payment decision for DiviTum TKa to pursue the gap-fill process during 2024. The gap-fill process is an established route to an anticipated own PLA pricing code. The process is used for unique tests where there are no comparable tests on the market. CMS will consider previously negotiated rates with private payers and charges for the test, and additional factors.

“We are eager to collaborate closely with CMS and embark on the gap-fill process. This established procedure will ensure that DiviTum TKa is priced appropriately. In this process, we will benefit from the commercial agreements already signed where rates have been established. Throughout the process, we will be able to bill for DiviTum TKa at a provisional price," said Warren Cresswell, President of the Americas at Biovica.

This preliminary Clinical Laboratory Fee Schedule (CLFS) payment decision is anticipated to be announced as final in December 2023 and Biovica plans to engage in the gap-fill process in 2024. The process is expected to take around one year and the PLA code along with its pricing is expected to be implemented from January 1, 2025. During the process, Biovica will continue to bill for Medicare services through its Medicare Administrative Contractor using a provisional price.

Contact

Anders Rylander, CEO
Phone: +46 76 666 16 47
E-mail: anders.rylander@biovica.com

Anders Morén, CFO
Phone: +46 73 125 92 46
E-mail: anders.moren@biovica.com

Biovica – Treatment decisions with greater confidence

Biovica develops and commercializes blood-based biomarker assays that help oncologists monitor cancer progression. Biovica’s assay, DiviTum® TKa, measures cell proliferation by detecting the TKa biomarker in the bloodstream. The assay has demonstrated its ability to provide insight to therapy effectiveness in several clinical trials. The first application for the DiviTum® TKa test is treatment monitoring of patients with metastatic breast cancer. Biovica's vision is: “Improved care for cancer patients.” Biovica collaborates with world-leading cancer institutes and pharmaceutical companies. DiviTum® TKa has received FDA 510(k) clearance in the US and is CE-marked in the EU. Biovica's shares are traded on the Nasdaq First North Premier Growth Market (BIOVIC B). FNCA Sweden AB is the company's Certified Adviser. For more information, please visit: www.biovica.com

This information is information that Biovica International is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-09-28 10:30 CEST.

Attachments

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