

Biovica receives final pricing decision for DiviTum TKa test by Medicare effective 1st January 2024

Biovica, active in cancer monitoring, today announces that the Center for Medicare & Medicaid Services (CMS) after reviewing public comments, has agreed with the minority CDLT panel to crosswalk DiviTum TKa to reimbursement code 0058U. The comments CMS received included detailed information as to how these tests are similar enough to make the crosswalk. Utilizing the Crosswalk pricing method, DiviTum TKa will be priced at USD322 per test effective from January 1st, 2024.

This CMS decision allows Biovica to bypass the previously announced pathway via the so-called Gapfill process, which would have entailed an additional year of engagement to establish pricing for DiviTum TKa.

The decision means there is a high probability to deliver in line with, or even above, the average price of \$400 per test that has previously been communicated, as established agreements with private actors are significantly higher in price.

"This is great news for Biovica! Being able to Crosswalk saves valuable time to established reimbursement and has substantial advantages for both patients and healthcare providers. An established DiviTum TKa price with CMS marks a significant achievement in our reimbursement strategy considering Medicare patients constitute about half of the total available market for DiviTum TKa. It provides pricing and payment certainty aligned with our previously communicated price levels," said Warren Cresswell, President Biovica Americas.

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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 2023-11-21 10:00 CET.

Attachments

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