Put It on the Board, 4/18

CMS changes proposed policy on NGS for cancer patients

The CAP and the Association for Molecular Pathology, in separate statements in March, lauded the Centers for Medicare and Medicaid Services for revising its national coverage determination on next-generation sequencing.

The CMS finalized its determination last month after changing what it had proposed last November in its memorandum titled “Next-generation Sequencing for Medicare Beneficiaries with Advanced Cancer.” The CAP and the AMP had recommended changes.

The final national coverage determination covers only NGS-based tests that the FDA has approved or cleared, CAP president R. Bruce Williams, MD, said March 21 in “Statline,” but “the final determination leaves the local Medicare Administrative Contractor with the discretion to cover all other tests as long as specific patient criteria are met.” The expanded criteria include recurrent, relapsed, refractory, metastatic, and advanced stage III or stage IV cancer, he added. Stage III was added in the final NCD.

The CMS removed the coverage with evidence development requirements from the final NCD.

The AMP said in a March 19 statement that it considers the change between the proposed and final NCD on NGS for Medicare beneficiaries with advanced cancer to be a “huge success” for its members, its advocacy partners, and cancer patients. “This new policy,” it said, “preserves patient access to the many clinically proven NGS-based Laboratory-Developed Procedures that are currently recognized as the standard of care in oncology diagnostics.”
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FDA approves new HPV test

Becton, Dickinson and Company received premarket approval from the Food and Drug Administration for its BD Onclarity HPV assay. The test detects 14 types of high-risk HPV from specimens collected in the BD SurePath liquid-based cytology vial. It identifies HPV types 16, 18, and 45 while concurrently detecting types 31, 33, 35, 39, 51, 52, 56, 58, 59, 66, and 68.

The FDA reviewed data collected during a multiyear, prospective, multicenter clinical trial conducted in the U.S. that included more than 33,500 vaccinated and nonvaccinated women. The test is clinically validated for use as a primary screening test, for triaging patients with abnormal Pap test results, and in combination with a Pap test.

The BD Onclarity assay is performed on the benchtop BD Viper LT system. It achieved the European CE-IVD mark in 2014, received regulatory approval in Canada and Japan in 2017, and is currently for sale in these and other markets.
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Roche launches Ventana DP 200 slide scanner

Roche last month launched the Ventana DP 200 high-speed slide scanner for digital pathology. Its tray-based design enables no-touch slide processing for fewer workflow errors, and it has a scan speed of less than 49 seconds for a 15 by 15-mm scan area, according to the company. Ann Costello, head of Roche Tissue Diagnostics, said in a statement that the launch of the scanner "provides a foundation for a future menu of Roche image analysis algorithms."

The Ventana DP 200 is Digital Imaging and Communications in Medicine Standard compatible and integrates with image management servers, including Ventana Virtuoso software. It is CE marked by the European Commission for IVD use and is available in the U.S. for research use only.
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FDA clears Quidel Sofia Lyme FIA for use with Sofia 2

Quidel received 510(k) clearance from the FDA to market its Sofia Lyme fluorescent immunoassay to be used with the Sofia 2 fluorescent immunoassay analyzer for the rapid differential detection of human IgM and IgG antibodies to *Borrelia burgdorferi* from serum and plasma specimens.

Sofia 2 is Quidel's next-generation version of its Sofia. Sofia 2 integrates wireless connectivity and its barcode scanner within a smaller footprint than the Sofia instrument. Quidel says it improved the graphical user interface and optics system. The Sofia 2 system comes connected to Virena, Quidel's data-management system, which provides aggregated, deidentified testing data in near real-time.

The Sofia Lyme assay was previously 510(k) cleared for use on the Sofia instrument. The new clearance allows the assay to also be run on the Sofia 2. The Lyme assay is the fourth 510(k)-cleared Sofia test for use on the Sofia 2. The others are the Influenza A+B assay, RSV assay, and Strep A+ assay.
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Oxford Gene Technology offers new Cytocell website

Oxford Gene Technology launched a new version of its Cytocell fluorescence in situ hybridization probes website.

The company created an interactive chromosome search tool designed to be familiar to cytogeneticists and facilitate the quick and easy identification of appropriate probes. The tool provides a visual representation of the chromosome using the International System for Human Cytogenetic Nomenclature G-banding. It also enables scrolling over the chromosome bands to pinpoint the location to be targeted by a probe.

The website includes a redesigned probe search function, allowing users to quickly locate probes by conducting a free text search or by filtering using a comprehensive set of probe filter options. New product pages make it easy to access more resources and simpler to request samples and quotes.

A revamped support section includes Cytocell's FISH 'n' Tips area, a collection of tips from Cytocell experts and soon to be opened up for contributions from users. The site also features instructional video content, including a detailed protocol video for pretreatment of formalin-fixed, paraffin-embedded samples prior to FISH.[hr]