A Shift Towards Therapeutic Group Labeling for Oncology Companion Diagnostics

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Background

Approved for use with oncology products, companion diagnostics are medical devices that improve cancer treatment by identifying patients who are most likely to benefit from an oncology product as well as patients who may have increased safety risks. In 2020, the Food and Drug Administration (FDA) released a draft guidance encouraging the development of companion diagnostics for use with therapeutic groups rather than with individual products. This study evaluates trends in companion diagnostic and associated therapeutic label language over time.

Methods

Label content for devices listed on the FDA's "List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)" website was reviewed for therapeutic and product specific language.

Results

As of October 1, 2021, a total of 45 companion diagnostics and 46 oncology products were identified. Of the 45 companion diagnostics, 22 (48.9%) were approved for use with 1 oncology product, 20 (44.4%) with 2-5 products, 2 (4.4%) with 6-10 products, and 1 (2.2%) with >10 products.
Two (4.4%) of the 45 diagnostics had label language denoting a therapeutic group. Cobas EGFR Mutation Test v2 received therapeutic group labeling in 2020, 7 years after initial approval. ONCO/Reveal Dx Lung & Colon Cancer Assay contained therapeutic group label language in the initial approval in 2021.

Conclusion

Two devices received therapeutic group labeling since release of the draft FDA guidance. This slow shift to incorporate therapeutic group labeling likely reflects the short time since release of the guidance as well as the low number of new devices approved.