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New Clinical Evidence Supports Ki-67 Use as Medically Necessary in the Treatment of Certain Breast Cancers

The FDA's recent approval of Verzenio® for the treatment of certain breast cancers supports reconsideration of the use of Ki-67 as a prognostic marker. The study monarchE (4) demonstrated that the use of Verzenio®, along with standard endocrine therapy, resulted in a significant increase in invasive disease-free survival for its patient population. In HR+ HER2-, high-risk, early breast cancer cases with Ki-67 scores of $\geq 20\%$, the study demonstrated these results when Verzenio® was provided with endocrine therapy versus endocrine therapy alone (3).

The Ki-67 score provides clinicians with an indication of risk of recurrence and improves the ability to make better treatment decisions. Patients with a high Ki-67 have a higher rate of cellular proliferation, and are more at risk of recurrence. Studies support the use of Ki-67 as a prognostic tool for disease-free survival (1, 2).

CMS' most recent update of Article A53704 in November, 2020 (5) indicates they still do not support the routine billing of Ki-67 in breast cancer cases, citing no proven standardized value has been established. The College of American Pathologists also does not currently recommend routine testing of Ki-67 of breast cancers, but does include this marker as an option on the breast biomarker template (6).

The clinical evidence demonstrated by this research trial (4) supports the use of Ki-67 for the treatment of certain breast cancers. The prognosis for patients identified as high-risk is significantly improved with the use of endocrine therapy and the addition of Verzenio®, and the level Ki-67 above or greater than 20% is a key determinant for the patient population.

The advancement of breast cancer treatment protocols extends the lives of patients. Given the latest research and potential for future treatment options, the Ki-67 level proves to be a valuable piece in improving the prognosis for breast cancer patients.

Resources

1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6776129/>
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8430879/>
3. <https://investor.lilly.com/news-releases/news-release-details/fda-approves-verzenior-abemaciclib-first-and-only-cdk46>
4. <https://clinicaltrials.gov/ct2/show/NCT03155997>
5. [CMS Article ID A53704](#)
6. [CAP Breast Biomarker Template \(2020\)](#)