Do Accelerated Approvals of Cancer Meds Measure Up?

Of the 129 indications that received accelerated approval during 2013—2023, 48 were converted to regular approval.

June 10, 2024 By Liz Highleyman

Only four out of 10 cancer drugs granted accelerated approval by the Food and Drug Administration (FDA) demonstrated a clinical benefit in follow-up trials, researchers recently reported.

The FDA may grant accelerated approval based on surrogate markers, such as overall response rate or progression-free survival. These therapies are expected to undergo further testing to confirm that they do, in fact, offer clinical benefits, such as improved overall survival or better quality of life.

Of the 129 indications that received accelerated approval during 2013—2023, 48 were converted to regular approval. Of these, 19 (40%) were converted based on overall survival, meaning 60% were based on surrogate measures. Among 46 indications with more than five years of follow-up, only 20 demonstrated a clinical benefit in confirmatory trials.

“Patients should be clearly informed about the cancer drugs that use the accelerated approval pathway and do not end up showing benefits in patient-centered clinical outcomes,” Ian Liu MD, JD, MPH, of Brigham and Women’s Hospital, and colleagues concluded.