PARTNERSHIP TO FIGHT CHRONIC DISEASE

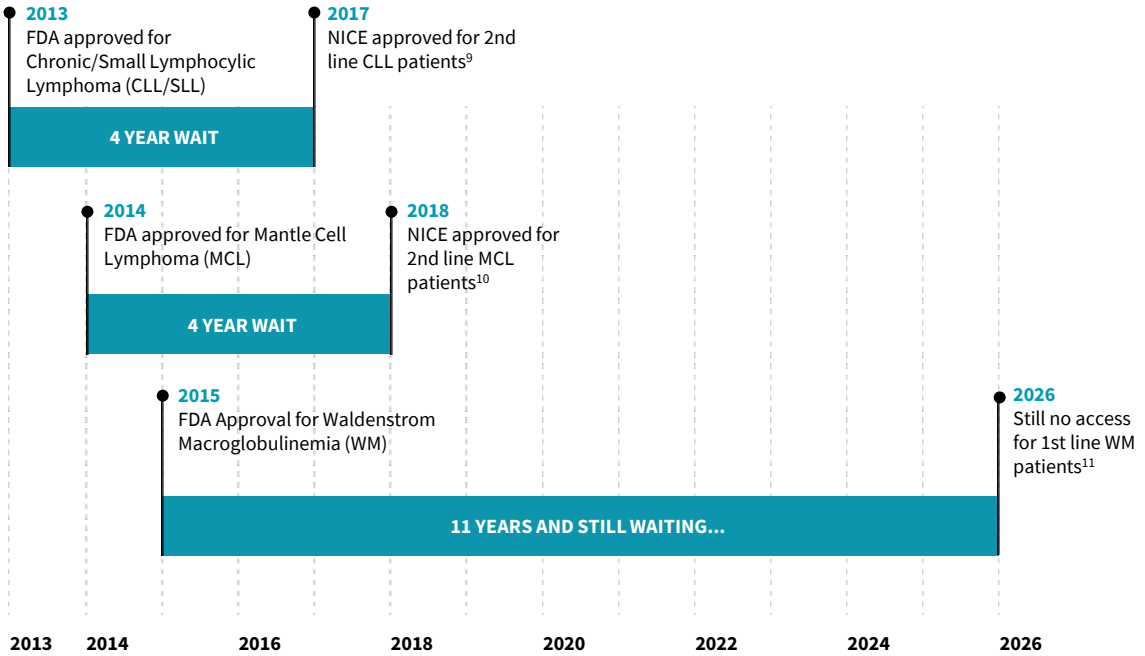
U.S. PATIENTS GAIN EARLY ACCESS TO CANCER MEDICINES WHILE U.K. PATIENTS GO WITHOUT

POLICYMAKERS MUST REJECT PROPOSALS TO IMPORT U.K. STANDARDS THAT DEVALUE OLDER ADULTS AND PEOPLE LIVING WITH CHRONIC CONDITIONS THROUGH "MOST FAVORED NATION" POLICIES

THE U.S. CONTINUES TO LEAD IN DRUG DEVELOPMENT AND MAKING NEW MEDICINES AVAILABLE TO PATIENTS.[1]
In nations like the U.K., regulatory approval lags far behind the U.S., and even after approval, public health agencies create added hurdles. The National Institute of Health and Care Excellence (NICE) – the U.K. agency that makes reimbursement recommendations to the government – requires additional approvals based on government cost-effectiveness thresholds like the Quality-Adjusted Life Year (QALY), causing access delays and restrictions.[2,3]

U.K. PATIENTS WITH CANCER WAIT UP TO 11+ YEARS FOR ACCESS TO NEW TREATMENT

U.S. patients with blood cancers have had broad access to Imbruvica (ibrutinib) since 2013 following its initial approval by FDA and funding by Medicare.[4] In contrast, U.K. patients have faced years of delays and restrictions due to the QALY-based thresholds employed by NICE.[5,6,7] Adoption of U.K. metrics through "Most Favored Nation" pricing proposals would apply the same low value to the lives of Americans with cancer, putting their access at risk.[8]



Note: Timeline understates access delays for many U.K. patients compared to the U.S., where Medicare covers any medically appropriate use after 2013 FDA approval.

BETTER ACCESS IN THE U.S. SAVES AND IMPROVES THE LIVES OF THOUSANDS OF AMERICANS LIVING WITH CANCER EACH YEAR

345 vs 191

More new cancer medicines are available in the U.S. than the U.K. Over twelve years, the U.S. launched 345 cancer drugs compared to 191 in the U.K.[12]

Overall survival is higher in the U.S. than the U.K. for patients with non-small cell lung cancer (NSCLC).[13,14] The U.K. only offers treatment aligned with clinical guidelines to approximately half of the recommended patient population with NSCLC.[15]

FIVE WAYS THE U.K. SYSTEMATICALLY BLOCKS PATIENT ACCESS TO NEW CANCER TREATMENTS

- **Uses QALYs to undervalue patients' lives** by assigning a lower value to years of life for patients with cancer relative to healthy individuals. As a result, medicines that extend or improve the lives of patients with cancer are rejected by NICE despite providing significant benefits for patients.

  Case in point: In 2024, NICE denied coverage for a breast cancer medicine that was already available for routine use in 18 European countries because of the formula NICE used to value the severity of breast cancer.[16]

- **Ignores outcomes that are important to patients living with cancer** like fatigue, neuropathy, and slower disease progression, as well as quality-of-life benefits like ability to return to work or care for family. As a result, NICE systematically undervalues medicines for these patients.

  Case in point: The ability to sleep and maintaining relationships with loved ones are common concerns for patients with breast cancer – both of which are omitted by NICE in their value assessments.[17]

- **Demands unnecessary additional evidence** on medicines that have already demonstrated clinical benefit for patients, delaying access to new treatments. By waiting years until longer-term results are available, the U.K. rigs the system against patients who don't have time to wait.

  Case in point: 77% of cancer medicines that received FDA accelerated approval were either rejected by NICE or never evaluated at all, largely because NICE demanded longer-term outcomes that required additional years of validation.[18]

- **Ignores real world evidence on how cancer medicines work,** including data on outcomes for different subgroups of patients, and medicines' results in everyday clinical practice. These data are commonly captured from sources such as registries or health claims but are often ignored by NICE in their funding decisions.

  Case in point: NICE rejected a commonly used medicine for advanced colorectal cancer for years despite real-world evidence showing the medicine can shrink tumors to the point that enables many patients affected to become newly eligible for curative surgery.[19]

- **Imposes narrow coverage restrictions,** even when new evidence shows broader use could be beneficial. In the U.S., by contrast, cancer medicines are commonly covered for many medically beneficial uses beyond those in FDA-approved labeling.

  Case in point: One cancer medicine first approved by the FDA in 2014 is used to treat dozens of different types of cancers in the U.S.,[20] but NICE has only approved it to treat a few cancer indications in the U.K. For other uses, doctors are unable to prescribe and obtain coverage for the medicine in the U.K.[21]

Learn more about the unintended consequences of "Most Favored Nation" at
www.fightchronicdisease.org/MFN

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