Measuring the Impact of HTA on Patient Access to New Medicines in NHS England: A Comparison of Public Health Insurance Funding Restrictions and Patient Uptake for New Medicines Across the United Kingdom, France, Germany, and the United States

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BACKGROUND

Patient access to new medicines in many countries depends largely on whether the medicine is reimbursed by public health insurance. In the United Kingdom (UK) and several other countries, patients may face access barriers even for medicines that are reimbursed by public health insurance because only some approved uses are reimbursed (1). In the UK, the National Institute for Health and Care Excellence (NICE) recommends whether a new medicine should be funded for reimbursement in the National Health Service (NHS) by reviewing clinical evidence and performing cost-effectiveness analyses (2).[1] NICE health technology assessments (HTA) result in medicines receiving a positive or negative recommendation (3). A negative HTA outcome means a medicine is not recommended for reimbursement. A positive HTA outcome means a medicine is recommended for reimbursement; however, a positive NICE recommendation may restrict access by only recommending reimbursement for a subset of the population of patients approved by a medicine's market authorization (4). NICE refers to positive recommendations with added clinical criteria restrictions for reimbursement as 'optimized.'

In France, the French National Authority for Health (Haute Autorité de Santé or HAS) recommends whether a medicine should be funded for reimbursement in the French Social Security Scheme (5). Like NICE, the HAS can restrict access by only recommending reimbursement for some approved uses (1). In Germany, the Joint Federal Committee (Gemeinsamer Bundesausschuss or G-BA) determines a medicine's added clinical benefit, sometimes differentiating the added clinical benefit for various subpopulations within a market authorization; however, G-BA assessments are only used to inform price-setting, and no clinical criteria restrictions are placed on reimbursement (6).[2] In the United States, there is no government HTA entity imposing restrictions on reimbursement by public health insurance (Medicare and Medicaid); however, private plans in Medicare and Medicaid can impose utilization controls via patient cost-sharing tiers and step therapy (7).

RESEARCH OBJECTIVES

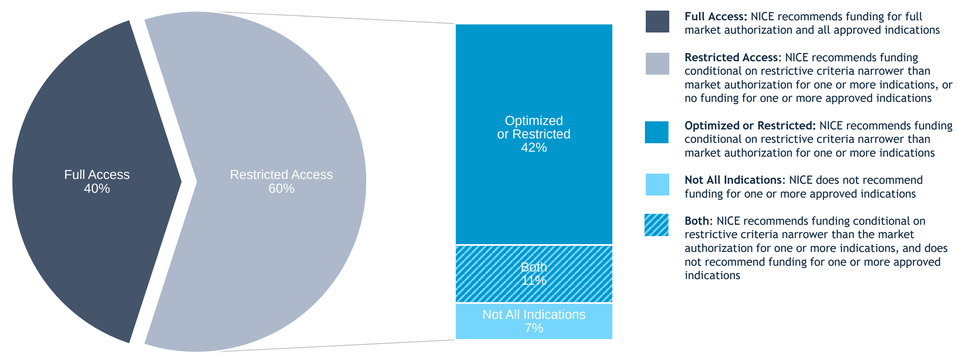
This study measures the impact of HTA on patient access to new medicines in NHS England by comparing public health insurance funding restrictions and the number of patients treated per capita across the United Kingdom, France, Germany, and the United States.

METHODS

- New medicines were identified as new active substances approved by the European Medicines Agency (EMA), Food and Drug Administration (FDA), or Pharmaceuticals and Medical Devices Agency (PMDA) and launched globally between January 1, 2017, and December 31, 2023.
- NHS reimbursement status was determined for each new medicine by reviewing all publicly available NICE technology assessments (TA) and other NICE guidance documents. A new medicine's NHS reimbursement status was deemed "restricted access" if there was a positive NICE recommendation that imposed additional clinical criteria restrictions for any approved indication, or if NICE gave a negative recommendation or if there was a terminated TA for some but not all approved indications.
- NICE recommendations were determined to impose additional clinical criteria restrictions on reimbursement if the patient population recommended by NICE was narrower than the market authorization. Most, but not all, of the positive NICE recommendations determined to be restricting access were also labelled by NICE as 'optimized.' NICE recommendations for use in the Cancer Drugs Fund (CDF) were assessed the same as NICE recommendations that are not for use in the CDF. In addition, NICE recommendations were not considered "restricted access" simply for requiring the use of a managed access agreement.
- Reimbursement status in the French Social Security Scheme was determined for each new medicine by reviewing all publicly available actual medical benefit (SMR) ratings by the HAS. A new medicine's reimbursement status in the French Social Security Scheme was deemed "restricted access" if there was a SMR rating greater than insufficient for some approved uses and a SMR rating of insufficient for other approved uses.
- Reimbursement status in Germany's Statutory Health Insurance was determined for each new medicine by its listing on the Lauer-Taxe. A new medicine's SHI reimbursement status was deemed "restricted access" if the G-BA applies a Drug Directive, or if the new medicine also had a life-style indication (e.g., weight-loss).
- Reimbursement status in the United States's Medicare and Medicaid program was determined by FDA approval and a record of launch in the United States. A new medicine's reimbursement status in Medicare and Medicaid was deemed "restricted access" if the medicine had a life-style indication (e.g., weight-loss).
- Estimates of the number of patients treated by each new medicine in each country (UK, France, Germany, USA) was based on the authors' analysis of sales, volume, treatment duration, and patient uptake from several data sources.

In the United Kingdom, NICE Can Recommend Funding for All or Some Part of Marketing Authorization

Percentage of NICE-Recommended New Medicines with Full vs. Restricted Access
(of all new medicines launched globally from 2017 to end of 2023)

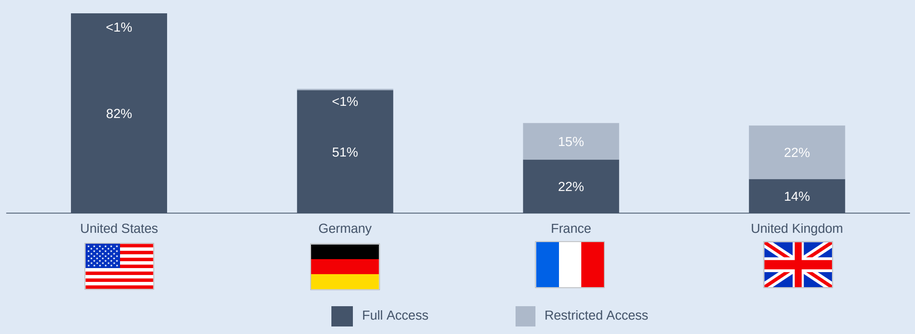


RESULTS

Our analysis indicates that patients in NHS England have worse access to new medicines than do public health insurance patients in France, Germany, and the United States. NHS England patients have a smaller share of new medicines funded for reimbursement and they face more "access restrictions" on the funding of new medicines that are reimbursed, such that not all approved uses are reimbursed. In addition, our analysis suggests that even for the fewer new medicines that NICE recommends for reimbursement, patients in the United Kingdom are less likely to access these medicines compared to patients in France, Germany, and the United States.

Only 14% of New Medicines are Recommended by NICE Without Restrictions and for All Approved Indications

Percentage of New Medicines Reimbursed by Public Insurance Plans with Full vs. Restricted Access by Country
(of all 376 new medicines launched globally from 2017 to end of 2023)



Patient Uptake

Analysis of the number of patients treated with NICE-recommended new medicines per capita suggests that even for the fewer new medicines that NICE recommends, patients in the UK are less likely to access those new medicines compared to patients in France, Germany, and the United States due to access restrictions: For every 100 patients treated with NICE-recommended new medicines in France, only 80 are treated in the UK; for every 100 patients treated with NICE-recommended new medicines in the United States, only 60 are treated in the UK; and for every 100 patients treated with NICE-recommended new medicines in Germany, only 40 are treated in the UK.

Limitations

Our analysis of the relative number of patients treated per capita as a measure of the "impact' of access restrictions on NICE-recommended new medicines assumes disease incidence and prevalence are similar across countries, as well as the alternative treatment options available in each country. In addition, the data for the number of patients treated with new medicines is country-level, and not specific to treatments funded by public health insurance. In the UK, NHS Scotland's SHTG may differ from NICE in its recommendations. Each country, especially the United States, also has private health insurance, which may offset access restrictions in public health insurance or impose other restrictions.

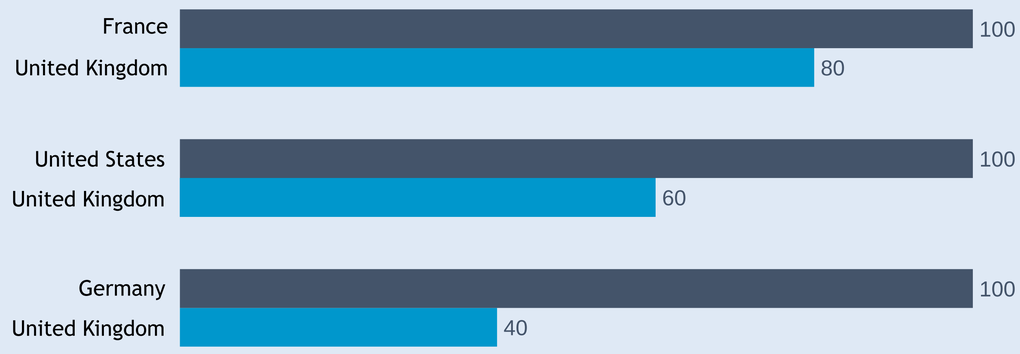
Funding Restrictions

Analysis of the number of new medicines funded for reimbursement in NHS England compared to public health insurance in France, Germany, and the United States shows that patients in NHS England have fewer new medicines funded for reimbursement: Patients in NHS England have 36% of new medicines funded for reimbursement, compared to 82% in the United States, 51% in Germany, and 37% in France.

As a result of government-imposed clinical criteria restrictions on funding for reimbursement, patients in NHS England have unrestricted reimbursement funding for far fewer new medicines compared to public health insurance in France, Germany, and the United States: Patients in NHS England have "unrestricted access" to 14% of new medicines, compared to 82% in the United States, 51% in Germany, and 22% in France.

Fewer Patients Access NICE-Recommended New Medicines in the UK vs. in Other Countries

Median Number of UK Patients Receiving NICE-Recommended New Medicines
(Per 100 Patients in Comparator Countries in 2023)



CONCLUSION

We found that patients in NHS England have worse access to new medicines than do public health insurance patients in France, Germany, and the United States. NHS England patients have access to a smaller share of new medicines that are funded for reimbursement. These patients also have more restrictions placed on the funding of new medicines that are reimbursed, such that not all approved uses are reimbursed. Our analysis suggests that funding restrictions do have an impact on patients, significantly reducing the number of NHS England patients being treated with new medicines compared to other countries. The funding for new medicines in the NHS, and the current methods used to allocate those limited funds, may be harming patients. This finding is especially concerning, given that recent NICE policies like the replacement of the end-of-life adjustment with the severity modifier are expected to further limit access to new medicines, rather than improve it (8,9,10). Further research should attempt to also compare relevant health outcomes across countries to the extent possible.

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*Joint first authorship [1] NICE recommendations apply to the NHS in England, Wales, and Northern Ireland. The Scottish Health Technologies Group (SHTG) performs HTA for NHS Scotland. [2] In Germany, the G-BA has applied clinical criteria restrictions on reimbursement through a Drug Directive to three products: alirocumab, evolocumab, and inclisiran. In both Germany and the United States, public health