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Analysis of Access Restrictions for New Medicines in the United Kingdom

November 2023

Introduction

Patient access to new medicines depends largely on reimbursement by public health insurance. In the United Kingdom and several other countries, patients face access barriers even for medicines covered by public health insurance because only some approved uses are reimbursed.

PhRMA's **Global Access to New Medicines Report** examines the launch and public health insurance reimbursement of new medicines across 72 different markets. This report examines access restrictions in public health insurance in the United Kingdom compared to France, Germany and the United States.

Throughout this report, new medicines refer to new active substances approved by the FDA, EMA, or PMDA and launched globally between January 1, 2017, and December 31, 2021.

Understanding Patient Access to New Medicines

In Many Countries, Patient Access Depends on Public Insurance Coverage

Access Restricted by Public Program

- Medicine is covered by public insurance
- Patients face access restrictions because public insurance only reimburses some approved uses

Full Access by Public Program

- Medicine is covered by public insurance
- Patients have full access because public insurance reimburses all approved uses

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Defining Full vs. Restricted Access by Country

United Kingdom

Patients have **full access** if the National Institute for Health and Care Excellence (NICE) recommends funding for the full marketing authorization (MA) and all EMA-approved indications. Patients have **restricted access** if NICE recommends funding conditional on criteria narrower than the MA or not for all EMA-approved indications.

France

Patients have **full access** if the Haute Autorité de Santé (HAS) rates Actual Medical Benefit (SMR) as greater than "Insufficient" for the full MA and all EMA-approved indications. Patients have **restricted access** if HAS rates SMR as "Insufficient" for any part of the MA or any EMA-approved indication.

Germany

Patients have **full access** if the medicine is listed on the Lauer-Taxe and not on the Federal Joint Committee (G-BA) exclusion list for lifestyle drugs. Patients have **restricted access** if the G-BA issues an exclusion or Drug Directive that restricts reimbursement within the MA or from some EMA-approved indications.

United States

Patients have **full access** if the medicine is reimbursed in the Medicare or Medicaid programs and approved by the FDA. Patients have **restricted access** if the new medicine is approved for other indications not covered by Medicare (*e.g.*, weight loss).

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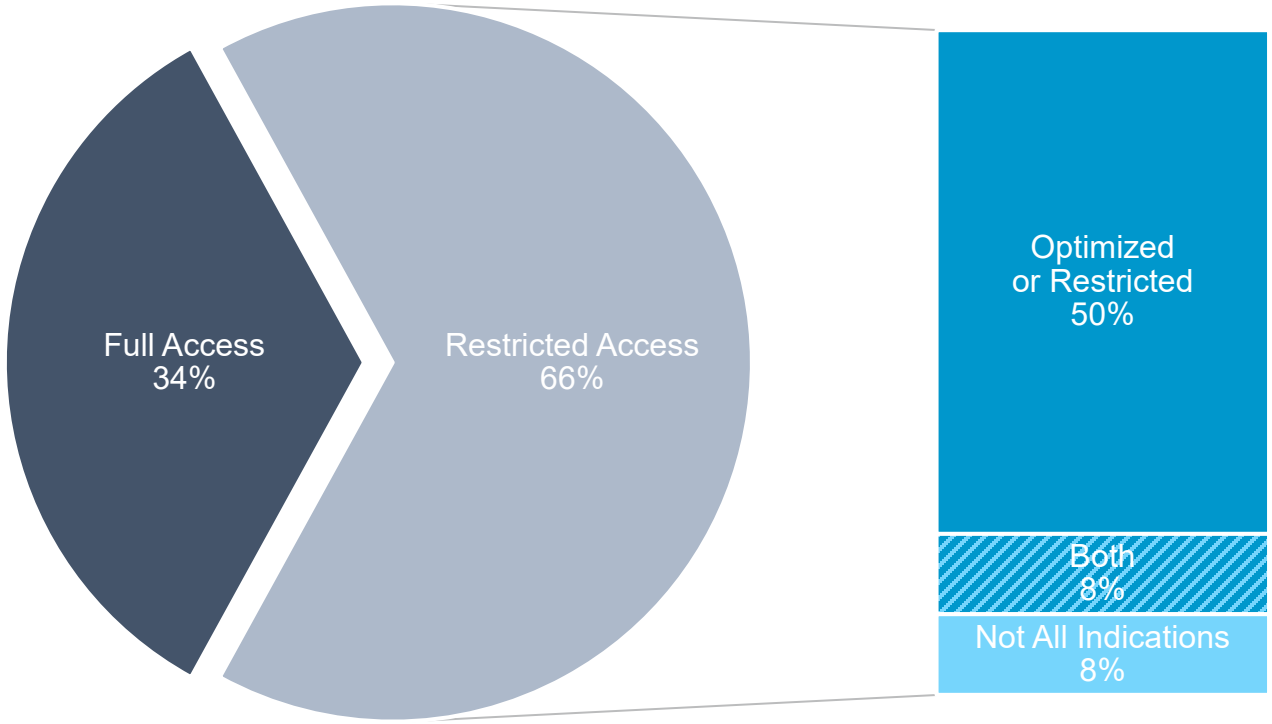
Note: In the United Kingdom, NICE recommendations apply to the National Health Service (NHS) in England, Wales and Northern Ireland. In France, HAS makes recommendations to the Economic Committee for Health Products (CEPS). In Germany, the G-BA has applied reimbursement restrictions through a Drug Directive to three products: alirocumab, evolocumab, and inclisiran (only inclisiran is included among new medicines launched globally between January 1, 2017, and December 31, 2021). For both Germany and the United States, the public health insurance programs exclude coverage for lifestyle indications.

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

Percentage of NICE-Recommended New Medicines with Full vs. Restricted Access (of all new medicines launched globally from 2017 to end of 2021)



Full Access: NICE recommends funding for full market authorization and all approved indications

Restricted Access: NICE recommends funding conditional on restrictive criteria narrower than market authorization for one or more indications, or no funding for one or more approved indications

Optimized or Restricted: NICE recommends funding conditional on restrictive criteria narrower than market authorization for one or more indications

Not All Indications: NICE does not recommend funding for one or more approved indications

Both: NICE recommends funding conditional on restrictive criteria narrower than the market authorization for one or more indications, and does not recommend funding for one or more approved indications

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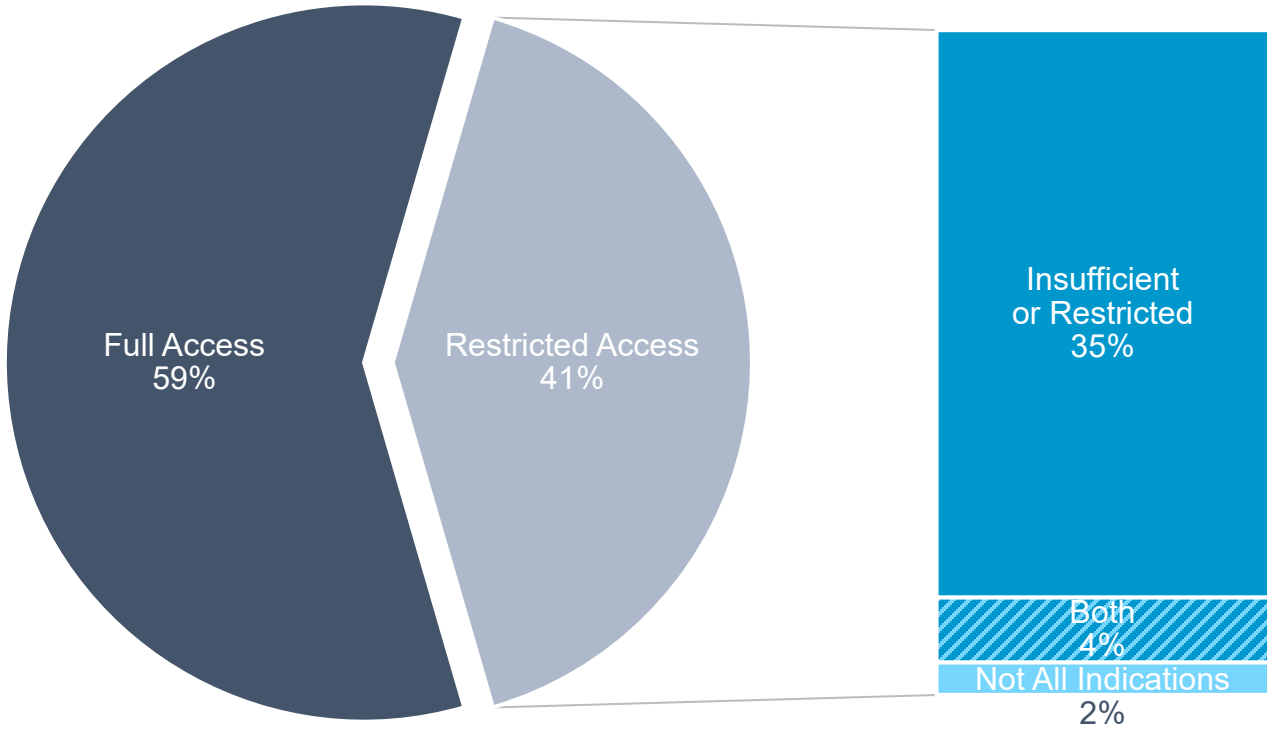
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2017, and December 31, 2021. Access in the United Kingdom is based on comparisons of NICE Technology Assessments and Guidance with EMA marketing authorizations through December 31, 2022. NICE recommendations apply to the NHS in England, Wales and Northern Ireland.

In France, HAS Can Recommend Funding for All or Some Part of the Marketing Authorization

Percentage of HAS-Recommended New Medicines with Full vs. Restricted Access (of all new medicines launched globally from 2017 to end of 2021)



Full Access: HAS rates Actual Medical Benefit (SMR) as greater than "Insufficient" for the full marketing authorization and all approved indications

Restricted Access: HAS rates SMR as greater than "Insufficient" conditional on restrictive criteria narrower than the marketing authorization for at least one approved indication, or SMR as "Insufficient" for at least one approved indication

Insufficient or Restricted: HAS rates SMR as greater than "Insufficient" conditional on restrictive criteria narrower than marketing authorization for at least one indication

Not All Indications: HAS rates SMR as "Insufficient" for one or more approved indications

Both: HAS rates SMR as greater than "Insufficient" conditional on restrictive criteria narrower than the marketing authorization for at least one approved indication, and SMR as "Insufficient" for at least one approved indication

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Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2017, and December 31, 2021. Access in France is based on comparisons of HAS SMR assessments with EMA marketing authorizations through December 31, 2022. HAS makes recommendations to the CEPS, which determines pricing and the placement of products on the positive reimbursement list.

Results of Country Comparisons

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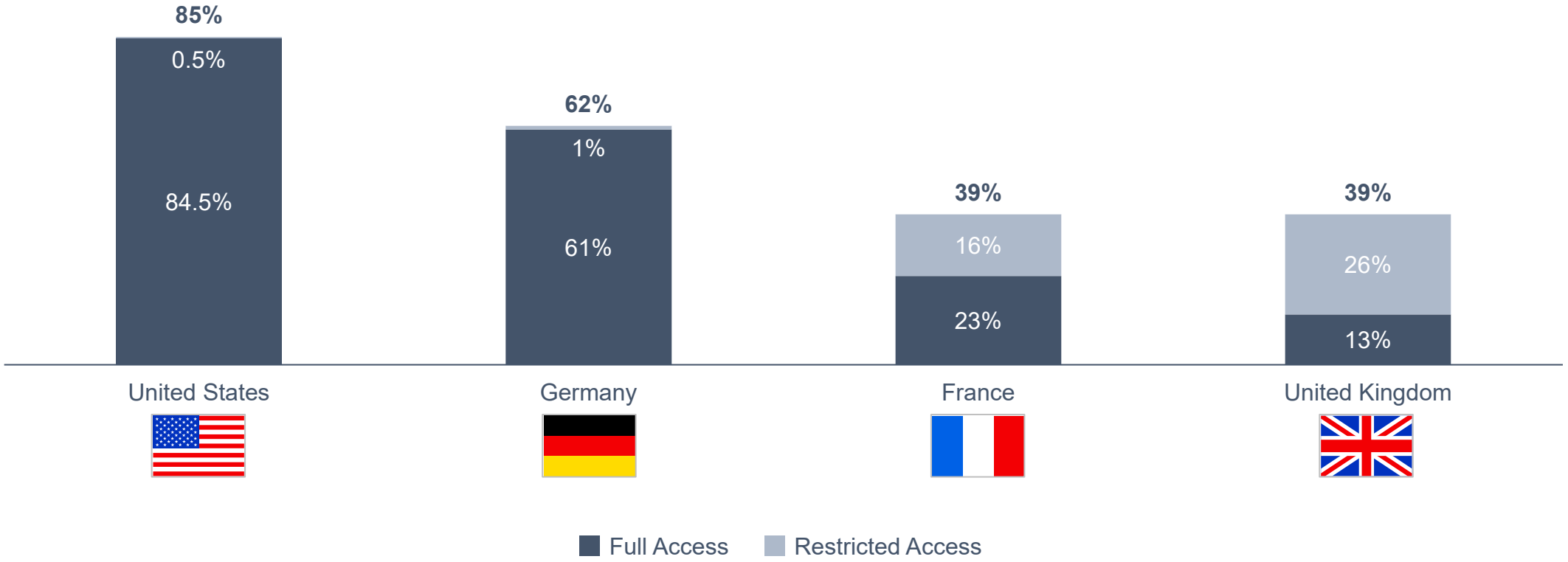
Only 13% of New Medicines Are Recommended by NICE Without Restrictions and for All Approved Indications

Percentage of New Medicines Reimbursed by Public Insurance Plans with Full vs. Restricted Access by Country (of all 269 new medicines launched from 2017 to end of 2021)



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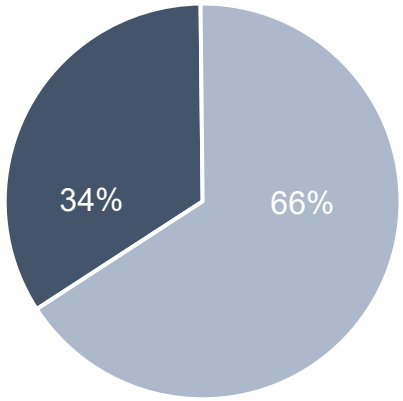
Source: PhRMA analysis of IQVIA MIDAS® and country regulatory and public insurance reimbursement data. November 2023.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2017, and December 31, 2021. Access is based on comparisons of EMA marketing authorizations with UK NICE technology assessments and guidance, France HAS SMR assessments, Germany G-BA Drug Directives and non-exclusion of listed medicines; and FDA marketing authorizations with reimbursement in Medicare and/or Medicaid through December 31, 2022. NICE recommendations apply to the NHS in England, Wales and Northern Ireland.

NICE Recommends Restricted Access for Two-Thirds of the New Medicines It Recommends

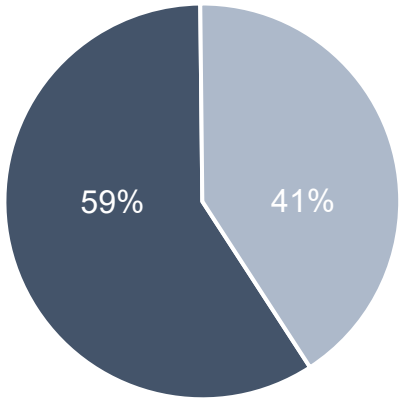
Full vs. Restricted Access Share of New Medicines Reimbursed by Public Plans

United Kingdom



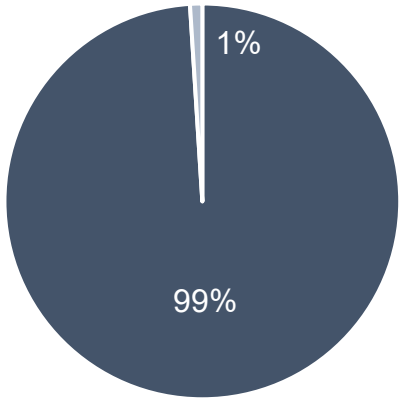
Reimbursed: NICE issues a positive recommendation for any part of the product's marketing authorization

France



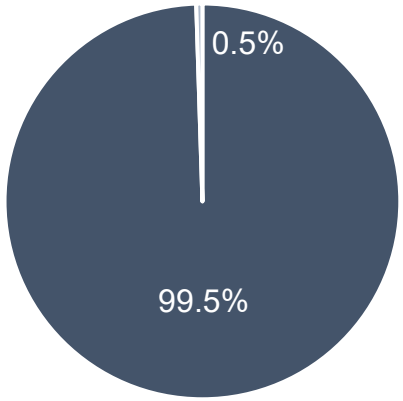
Reimbursed: HAS rates SMR as greater than "Insufficient" for any part of the product's marketing authorization

Germany



Reimbursed: G-BA does not exclude the product from reimbursement

United States



Reimbursed: Medicare and/or Medicaid covers the product

Full Access Restricted Access

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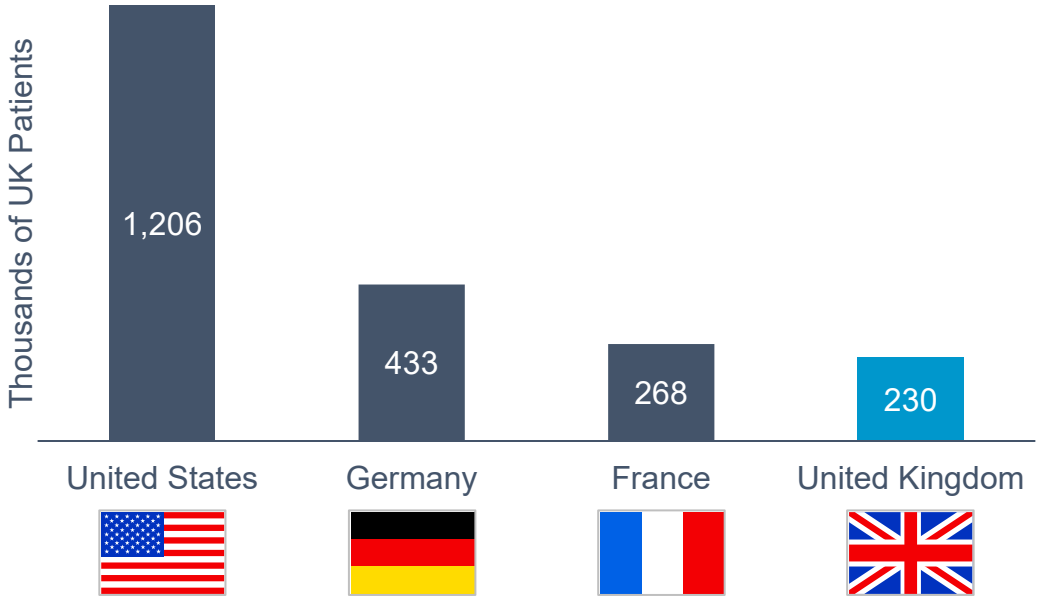
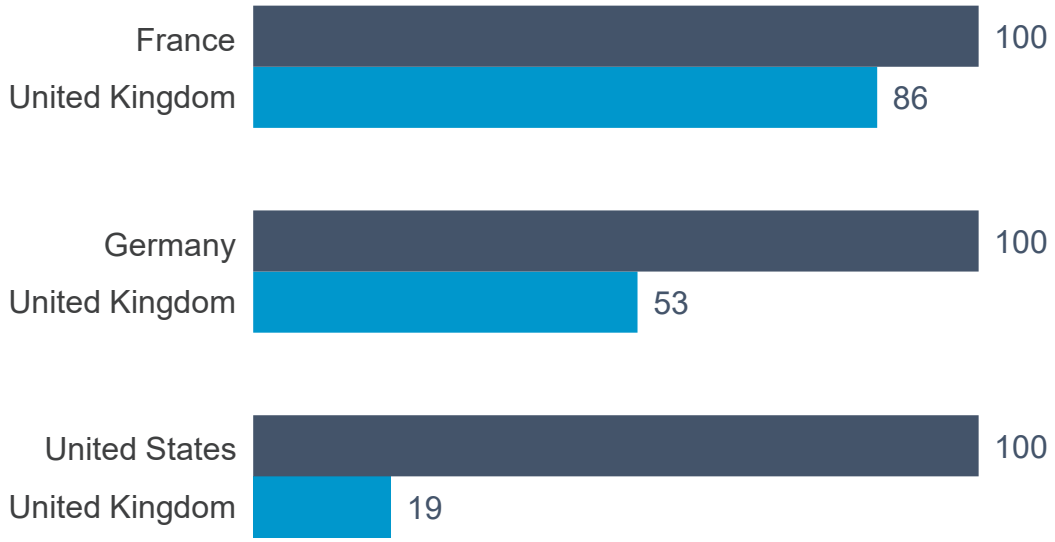
Fewer Patients Access NICE-Recommended New Medicines in the UK vs. in Other Countries

Number of Patients Receiving NICE-Recommended New Medicines (Adjusted to UK Population Size in 2022)



Number of UK Patients Receiving NICE-Recommended New Medicines (Per 100 Patients in Comparator Countries in 2022)



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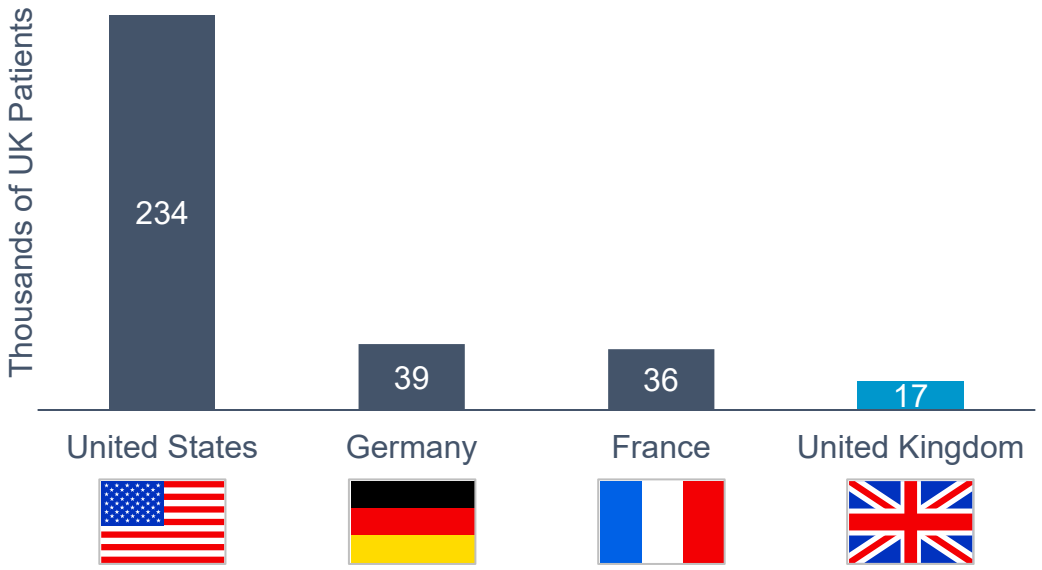
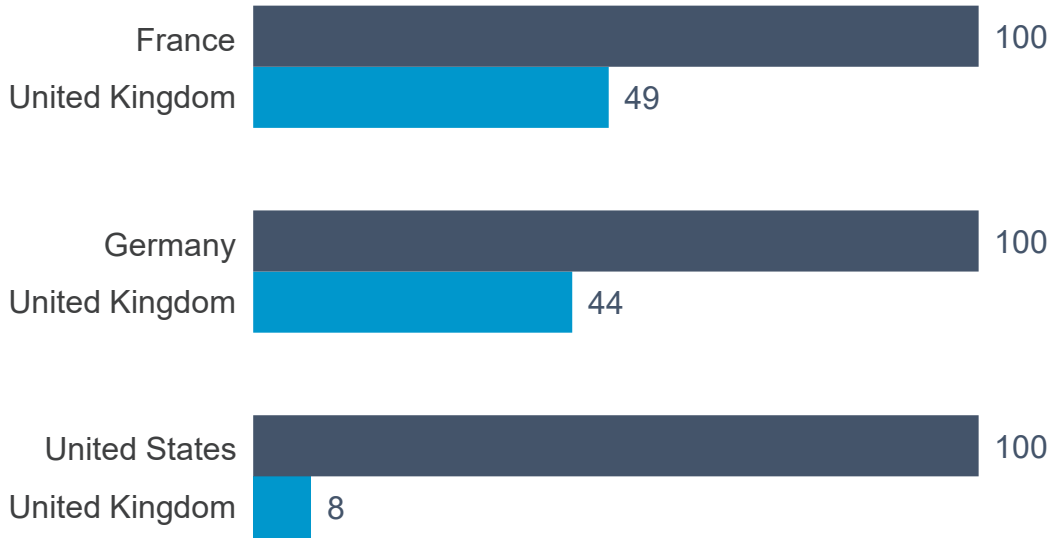
Source: PhRMA analysis of IQVIA MIDAS® and country regulatory and public insurance reimbursement data. November 2023.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2017, and December 31, 2021. NICE-recommended new medicines received positive NICE technology assessments or guidance for at least one approved indication through December 31, 2022. NICE recommendations apply to the NHS in England, Wales and Northern Ireland.

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

Number of Patients Receiving NICE-Recommended New Cancer Medicines (Adjusted to UK Population Size in 2022)



Number of UK Patients Receiving NICE-Recommended New Cancer Medicines (Per 100 Patients in Comparator Countries in 2022)



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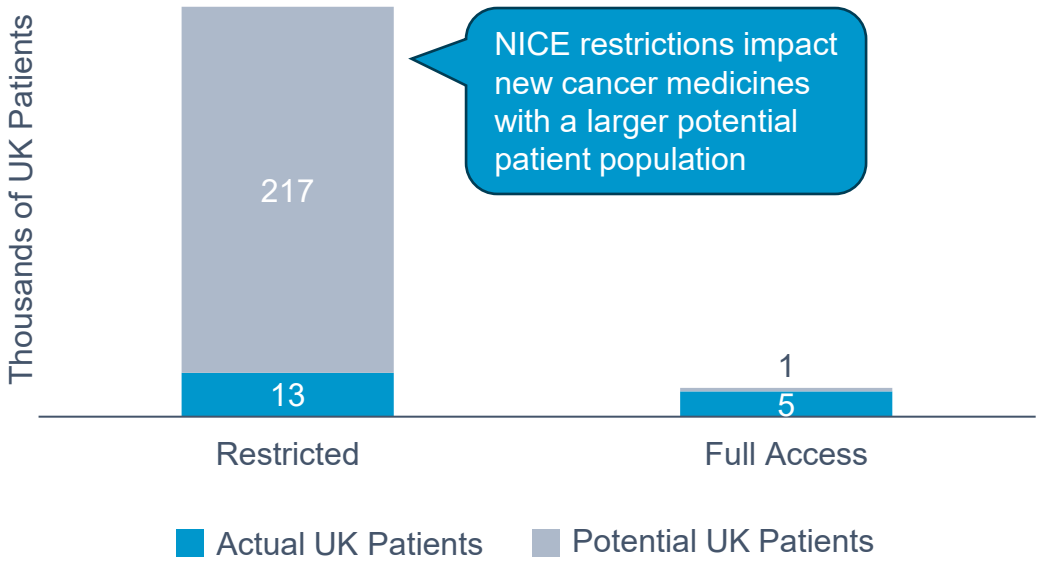
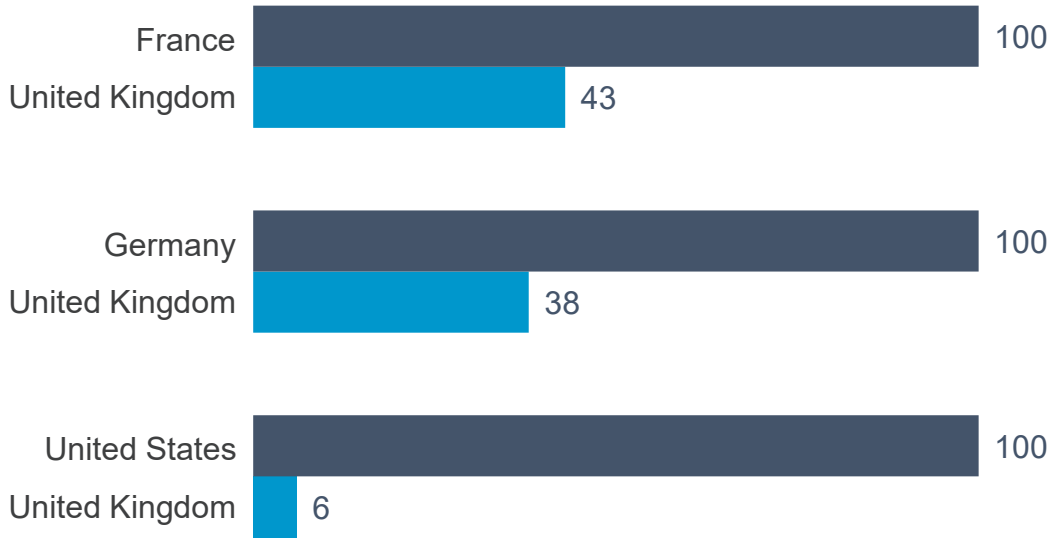
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2017, and December 31, 2021. NICE-recommended new cancer medicines received positive NICE technology assessments or guidance for at least one approved indication through December 31, 2022. NICE recommendations apply to the NHS in England, Wales and Northern Ireland.

NICE "Optimized" Recommendations Seriously Restrict Patient Access to New Cancer Medicines in the UK

Number of Potential UK Patients Not Receiving NICE-Recommended New Cancer Medicines (Adjusted to UK Population Size in 2022)



Number of UK Patients Receiving New Cancer Medicines Recommended for Restricted Access (Per 100 Patients in Comparator Countries in 2022)



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Methodology

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Comparing the Number of Patients Treated

Number of Patients Treated is based on estimates provided by IQVIA Patient Link. IQVIA estimates are by country and based on observed product sales volumes plus product- and disease-specific information on average daily dosages, treatment durations and adherence.

Adjusted to UK Population Size is calculated by applying country-specific per-capita uptake rates (number of patients treated divided by the country population) to the population of England, Wales and Northern Ireland. This allows comparisons to show country differences in the number of patients treated that are not due to differing country population sizes.

Per 100 Patients In Comparator Country is calculated using the ratio of the number of patients treated per capita in the United Kingdom over the number of patients treated per capita in each comparator country (France, Germany and the United States).

Potential UK Patients is the number of UK patients that would receive new medicines if the UK uptake rate were equal to the highest comparator country, less the actual number of UK patients receiving new medicines.

Time Period of Analysis is calendar year 2022. Estimates are based only on new medicines with positive NICE recommendations prior to 2022.

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