A Comparison of the Evolution of Payer Management Practices in Oncology in the US, Germany, France, and the UK, Over the Past Five Years

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BACKGROUND AND OBJECTIVES

- Research conducted in 2017 found that health technology assessment (HTA) processes provide European payers with a stronger value-based process for making coverage decisions for oncology medicines than their counterparts in the United States (US).
- In 2017, oncology drug management in the US was limited, and tools modeled to use value as a criterion for drug management were not widely implemented.
- Increased competition in certain oncology indications since 2017 led to the question of whether US payer management has evolved.
- This research assesses whether US management tools are approaching European HTA-like assessment tools.

METHODOLOGY

UNITED STATES

- A literature review was conducted to understand US Food and Drug Administration approvals in non-small cell lung cancer (NSCLC) and chronic lymphocytic leukemia (CLL) since 2018.
- Prices and payer management for products in NSCLC and CLL were analyzed.
- An online survey was developed based on findings from secondary research and otherwise mirrored a survey sent in 2017.
- The survey was sent to 21 payers and the sample matched the sample from the 2017 research; in some scenarios a payer from the same organization was not available to respond to the research so an individual in the same role from a similar organization was included in the sample.
- The survey included questions about the budget impact and management priority of oncology drugs, current management tools employed, and tools expected to be employed in the future. It also included specific questions about management of branded products in NSCLC and CLL.

GERMANY, FRANCE, AND THE UNITED KINGDOM

- A literature review was conducted to understand European Medicines Agency approvals in NSCLC and CLL since 2018.
- List prices for each product were analyzed in Germany, France, and the United Kingdom (UK).
- Gemeinsamer Bundesausshuss (GBA), Transparency Committee (TC), and National Institute for Health and Care Excellence (NICE) reports were reviewed for each new approval in NSCLC and CLL were reviewed to understand the rationale for reimbursement decisions for each product.
- Findings in Germany, France, and the UK were compared with findings in the US to understand key differences in reimbursement across markets and how product value is factored into these decisions in each market.

CONCLUSIONS

- The HTA process in Germany, France, and the UK continues to provide payers in these markets with a more value-based review process for oncology drugs compared with US payers. The price differential between the US and Europe for both branded monotherapies and combination therapies in NSCLC and CLL remain meaningful.
- Even in areas with a high level of competition, such as NSCLC and CLL, US payers provide largely unrestricted access to branded monotherapies and combination therapies. By contrast, payers in Germany, France, and the UK often restrict access based on clinical and cost considerations.
- Some value-based tools, however, are beginning to emerge in the US and should continue to be monitored. First, although use of pathways of care with and without downside financial risk for providers is still narrow, these tools are used by more payers today than five years ago. Pathways are sometimes more restrictive than NCCN guidelines. Restrictive pathways seem to affect older chemotherapies and products with biosimilar options more than newer branded treatments, but there are cases of pathways of care being implemented for branded products in both NSCLC and CLL. In addition, payers are more likely to shift financial risk to providers today than they were five years ago. These changes are still observed in a minority of plans, but it is possible that other plans may feel empowered to take similar action after seeing their colleagues at other organizations do so. Therefore, this will be important to monitor again in three to five years.
- In addition, policy changes may help US payers to better negotiate prices for oncology drugs in the future. Specifically, the Inflation Reduction Act includes legislation that would allow Medicare to negotiate drug prices beginning in 2026 for Medicare Part D (self-administered) drugs and in 2028 for Medicare Part B (physician-administered) drugs. It will be important to track the implementation of these policies with changes in political administration over the next four to six years.

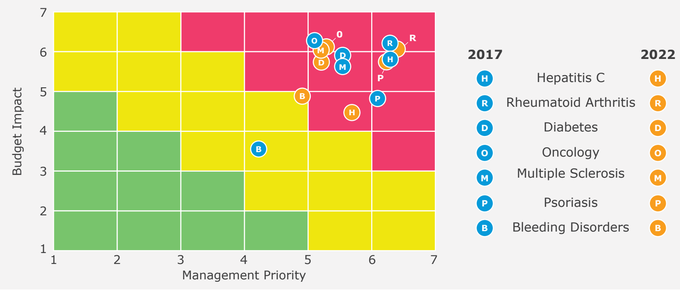
This work was supported and funded by Envision Value and Access.
All authors were employed by Envision during the publication.

RESULTS

US BUDGET IMPACT AND PAYER MANAGEMENT OF ONCOLOGY (2017 VS 2022)

Level of Management and Budget Impact – High-Cost Therapeutic Categories (2017 vs 2022)

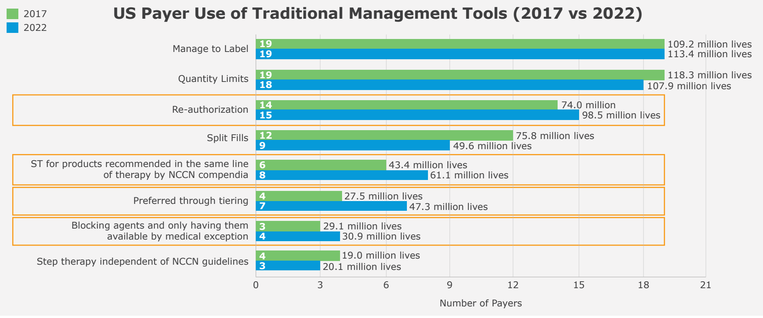
(weighted by covered lives, n=21, 120.1 million covered lives)



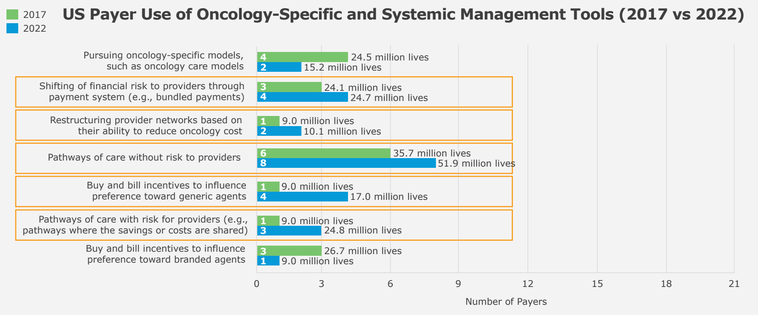
2017		2022
H	Hepatitis C	H
R	Rheumatoid Arthritis	R
D	Diabetes	D
O	Oncology	O
M	Multiple Sclerosis	M
P	Psoriasis	P
B	Bleeding Disorders	B

- In 2017, the budget impact of oncology in the US was the highest across all high-cost therapeutic categories identified, and in 2022 oncology remained the highest budget impact category.
- Despite the high budget impact, oncology was considered by US payers to be a moderate management priority in 2017 and 2022.
- In 2022, US payers continued to rely on traditional management tools in oncology. However, some more restrictive tools are beginning to emerge.
- Most notably, restrictive traditional tools such as step edits, tiering differentials, and blocking agents were more common in 2022.
- Oncology-specific and systemic tools have also emerged: pathways of care and mechanisms that shift financial risk to providers were more common in 2022 compared with 2017. However, these changes were observed at a limited number of organizations.

US Payer Use of Traditional Management Tools (2017 vs 2022)

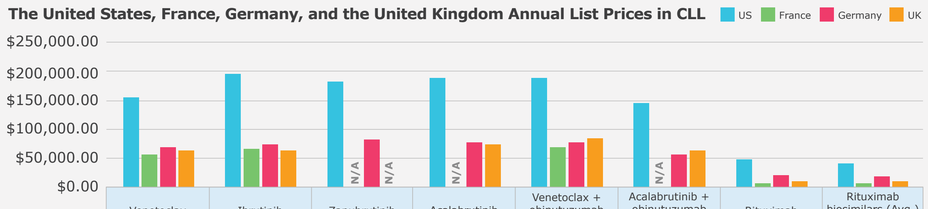


US Payer Use of Oncology-Specific and Systemic Management Tools (2017 vs 2022)



UNITED STATES, GERMANY, FRANCE, AND UNITED KINGDOM MANAGEMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA (2017 VS 2022)

The United States, France, Germany, and the United Kingdom Annual List Prices in CLL



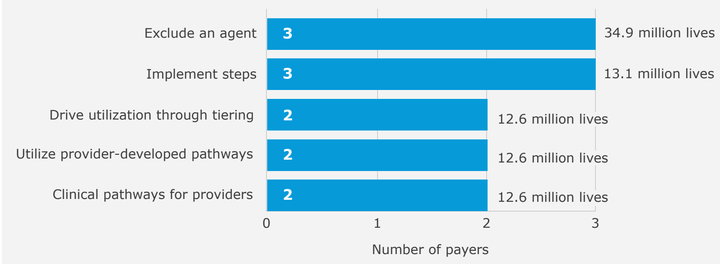
	Venetoclax (**Venclexta**)	Ibrutinib (**Imbruvica**)	Zanubrutinib (**Brukinsa**)	Acalabrutinib (**Calquence**)	Venetoclax + obinutuzumab (**Venclexta + Gazyva**)	Acalabrutinib + obinutuzumab (**Calquence + Gazyva**)	Rituximab (**Rituxan**)	Rituximab biosimilars (Avg.) (**Rituxan biosimilars**)
US	$154,600.34	$194,429.04	$181,961.00	$188,316.96	$188,005.93	$145,321.68	$48,855.04	$40,621.10
France	$57,051.24	$66,677.34	N/A	N/A	$70,260.84	N/A	$7,195.30	$7,195.30
Germany	$69,972.01	$74,565.56	$83,622.81	$78,747.09	$79,126.76	$57,114.62	$21,403.20	$18,273.75
UK	$65,181.99	$63,055.36	N/A	$74,316.71	$84,298.27	$64,240.50	$10,260.97	$9,235.11

- There were still significant price differences for branded agents in CLL between the US and European countries.
- Despite high drug prices, increased competition, and the availability of oral drugs that can be managed under the pharmacy benefit (where payers have better control), most payers managed branded products to label. However, the availability of biosimilars allowed US payers to take more restrictive action, for example, excluding agents where biosimilars were available.
- Management tools more restrictive than label were most commonly used at integrated delivery networks (IDNs) but in some cases were observed at national managed care organizations (MCOs) and pharmacy benefit managers (PBMs).
- Management was the same in the Commercial and Medicare books of business.
- In Germany, France, and the UK, most CLL agents had restricted reimbursement.
- In both Germany and France, ibrutinib was seen as having a higher clinical benefit than other treatments.
- In the UK, reimbursement for most CLL drugs was also restricted; however, some agents were recommended.

United States – Commercial and Medicare Management of CLL Treatments – More Strictly than Label (2017 vs 2022)

Product	No. of payers managing more strictly than label in 2017	No. of payers managing more strictly than label in 2022
Venetoclax **(Venclexta)**	2 of 21	0 of 21
Ibrutinib **(Imbruvica)**	2 of 21	2 of 21
Rituximab **(Rituxan)**	0 of 21	6 of 21
Rituximab biosimilars **(Rituxan biosimilars)**	N/A	2 of 21
Zanubrutinib **(Brukinsa)**	N/A	0 of 21
Acalabrutinib **(Calquence)**	N/A	0 of 21
Venetoclax + obinutuzumab **(Venclexta + Gazyva)**	N/A	0 of 21
Acalabrutinib + obinutuzumab **(Calquence + Gazyva)**	N/A	0 of 21

United States – Management Tools Employed in CLL in 2022



Germany, France, and United Kingdom Reimbursement in CLL

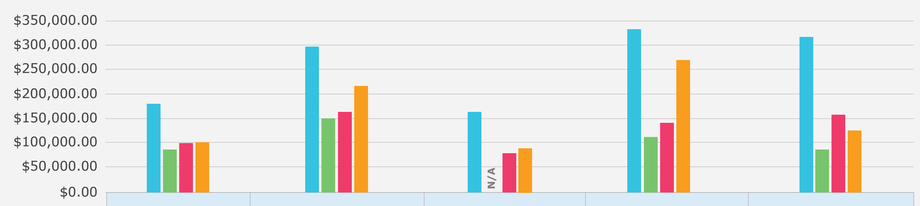
Highest recommendation | Mid-level or restricted recommendations | Not recommended

Drug	Germany GBA	France ASMR	United Kingdom NICE
Venetoclax **(Venclexta)**	No additional benefit	ASMR V	Recommended for use within Cancer Drug Fund in certain situations*
Ibrutinib **(Imbruvica)**	Non-quantifiable medical benefit	ASMR III	Recommended, simple discount
Rituximab **(Rituxan)**	N/A	Denied reimbursement	N/A
Rituximab biosimilars **(Rituxan biosimilars)**	No additional benefit	ASMR V	Recommended in certain situations**
Zanubrutinib **(Brukinsa)**	N/A	ASMR IV	Only recommended in combination with fludarabine and cyclophosphamide
Acalabrutinib **(Calquence)**	N/A	ASMR V	Recommended
Venetoclax + obinutuzumab **(Venclexta + Gazyva)**	No additional benefit	Early access authorization	Recommended for use within Cancer Drug Fund in certain situations*
Acalabrutinib + obinutuzumab **(Calquence + Gazyva)**	No additional benefit	N/A	N/A

*Recommended in certain patients and if the conditions in the managed access agreements are followed; **Recommended in certain patients when the commercial arrangements are followed.

UNITED STATES, GERMANY, FRANCE, AND UNITED KINGDOM MANAGEMENT OF NON-SMALL CELL LUNG CANCER (2017 VS 2022)

The United States, France, Germany, and the United Kingdom Annual List Prices in NSCLC



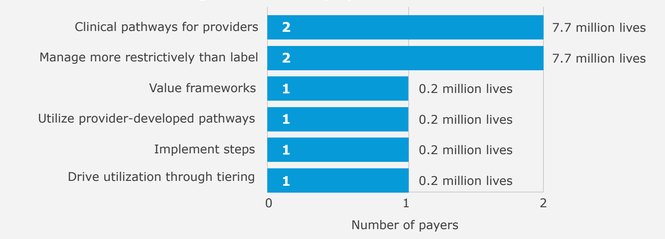
	Pembrolizumab (**Keytruda**)	Durvalumab (**Imfinzi**)	Cemiplimab-rwlc (**Libtayo**)	Nivolumab + ipilimumab (**Opdivo + Yervoy**)	Atezolizumab + bevacizumab (**Tecentriq + Avastin/Avastin biosimilars**)
US	$178,059.36	$298,928.76	$163,364.05	$328,486.88	$316,454.66
France	$86,385.43	$150,501.19	N/A	$112,478.60	$86,759.45
Germany	$101,159.19	$165,672.23	$75,788.01	$140,774.22	$160,404.31
UK	$101,044.60	$217,353.24	$89,326.50	$270,119.72	$124,408.95

- In NSCLC there were also significant price differences in listed prices across geographies.
- In NSCLC, products were administered by physicians and managed under the medical benefit, which gave payers less ability to control utilization.
- In 2017, only one small and tightly controlled IDN managed any therapy in NSCLC beyond label. Today, use of management tools more restrictive than label are still largely limited to IDNs, however, one national MCO representative indicated that his organization is managing products beyond label and implementing clinical pathways for providers.
- In Germany, the first two market entrants, pembrolizumab and durvalumab, were granted higher added benefit ratings than later entrants and combination therapies.
- In France, durvalumab was granted an ASMR III in patients who were not candidates for definitive chemoradiation or had metastatic NSCLC, expressing PD-L1 in ≥50% of tumor cells with no EGFR, ALK, or ROS1 aberrations, and could be used first line in these patients; the other products had an ASMR IV or V rating, limiting their reimbursement.
- In the UK, reimbursement for most CLL drugs was also restricted; however some agents were recommended.

United States – Commercial and Medicare Management of NSCLC Treatments – More Strictly than Label (2017 vs 2022)

Product	No. of payers managing more strictly than label in 2017	No. of payers managing more strictly than label in 2022*
Pembrolizumab **(Keytruda)**	1 of 21	1 of 21
Durvalumab **(Imfinzi)**	N/A	1 of 21
Cemiplimab-rwlc **(Libtayo)**	N/A	1 of 21
Nivolumab + ipilimumab **(Opdivo + Yervoy)**	1 of 21	1 of 21
Atezolizumab + bevacizumab **(Tecentriq + Avastin/Avastin biosimilars)**	N/A	1 of 21

Management Tools Employed in NSCLC in 2022



Germany, France, and United Kingdom Reimbursement in NSCLC

Highest recommendation | Mid-level or restricted recommendations | Not recommended

Drug	Germany GBA	France ASMR	United Kingdom NICE
Pembrolizumab **(Keytruda)**	Hint of a considerable added benefit	ASMR IV	Recommended, simple discount
Durvalumab **(Imfinzi)**	Considerable added benefit	ASMR III	Recommended in some situations*
Cemiplimab-rwlc **(Libtayo)**	No additional benefit	ASMR V	Not yet reviewed
Nivolumab + ipilimumab **(Opdivo + Yervoy)**	No additional benefit	ASMR IV	Not recommended
Atezolizumab + bevacizumab **(Tecentriq + Avastin/Avastin biosimilars)**	No additional benefit	ASMR V	Recommended in some situations*

*Both products only recommended in certain patients and reimbursement is based on commercial arrangements with the manufacturer.

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Ibrutinib for previously treated chronic lymphocytic leukemia and untreated chronic lymphocytic leukemia with 17p deletion or TP53 mutation. 5h. Zanubrutinib for untreated chronic lymphocytic leukemia [ID5079]. 5i. Acalabrutinib for treating chronic lymphocytic leukemia. 5j. Venetoclax with obinutuzumab for untreated chronic lymphocytic leukemia. 5k. Rituximab for the first-line treatment of chronic lymphocytic leukemia. 6. G-BA. (2017). Gemeinsamer Bundesausschuss. Retrieved 19 September, 2022, from https://www.g-ba.de/ . 6a. Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL). Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Pembrolizumab (new therapeutic indication: non-small cell lung carcinoma, squamous, first line, combination with carboplatin and (nab-) paclitaxel). 5b. Benefit assessment procedure for the drug durvalumab (non-small cell lung cancer, maintenance therapy). 6c. Resolution of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive: Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V Cemiplimab (new therapeutic indication: non-small cell lung cancer, first-line). 6d. Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V Nivolumab (New Therapeutic Indication: Non-small cell lung cancer, combination with ipilimumab and platinum-based chemotherapy, first-line). 6e. Benefit assessment procedure for the active ingredient atezolizumab (new indication: NSCLC, non-squamous, 1st line, combination with bevacizumab, paclitaxel and carboplatin; maintenance therapy). 6f. Benefit assessment procedure for the active substance venetoclax. 6g. Justification to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Ibrutinib (New Therapeutic Indication: Chronic Lymphatic leukemia, First-Line, in Combination with Obinutuzumab). 6h. Benefit assessment procedure for the active substance acalabrutinib (chronic lymphocytic leukemia, after at least 1 pretreatment). 6i. Justification to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Venetoclax (New Therapeutic Indication: Chronic Lymphocytic leukemia, First-line, in Combination with Obinutuzumab). 6j. 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Presented at ISPOR Europe 2022, 6-9 November 2022; Vienna, Austria and Virtual.