Examination of CMS National Coverage Analyses and Concordance with Other Decision-Making Bodies

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OBJECTIVES

• To examine trends in US CMS NCDs and identify correlations between NCDs and coverage recommendations by the US ICER and UK NICE.

BACKGROUND

- In recent years, the US Food and Drug Administration (FDA) has approved or considered approving new therapies with limited clinical evidence, with consequences for the public health care system and potential Medicare premiums levied.¹
- While US payers have the flexibility to alter Medicare premiums to account for changes in expected drug spending, a single-payer system reliant on tax revenue, such as the UK National Health Service (NHS), may have more restrictive access criteria as a result of less flexibility.

METHODS

- The Centers for Medicare & Medicaid Services (CMS) website was reviewed in January 2023 for completed national coverage decision (NCD) memos that were updated or created on or after 1 January 2017.
- Relevant NCD memos were filtered for decisions on medicinal products; for each appraisal, a pre-formatted extraction grid was used to capture information about the limitations, restrictions, and rationale for any NCD decisions.
- Assessments for therapeutic NCDs were searched for on the Institute for Clinical and Economic Review (ICER) and National Institute for Health and Care Excellence (NICE) websites to determine similarities in coverage decisions/recommendations.

RESULTS

- In the six year period from 2017–2023, 21 NCDs were issued, and only three were for medicinal products: monoclonal antibodies for the treatment of Alzheimer's Disease (aducanumab); chimeric antigen receptor (CAR) T-cell therapies for cancers (tisagenlecleucel and axicabtagene ciloleucel); and autologous blood-derived products (i.e. platelet-rich plasma [PRP]) for chronic non-healing wounds (Table 1).
- For both CAR T-cell therapies evaluated, CMS, ICER, and NICE were in agreement and recommended coverage for patients (**Figure 1**).
- ICER and NICE did not evaluate the use of plasma for chronic non-healing wounds, while the CMS NCD memo suggested mandatory coverage for 20 weeks, with use beyond that time frame subject to approval by local Medicare Administrative Contractors.
- CMS strictly regulated the coverage of anti-amyloid-beta monoclonal antibodies, which was in agreement with ICER's evaluation that aducanumab should not be covered at the expected annual price. NICE did not review aducanumab due to a lack of regulatory approval.

1 Comparison of access recommendations between CMS, ICER, and NICE

Therapy	Assessment agency	Date of assessment	Access decision recommended	Limitations or restrictions associated with therapy?	Other considerations
Anti-amyloid-beta monoclonal antibodies	CMS	7 April 2022	Access, with considerable restrictions	Coverage is only granted when individuals are enrolled in a CMS-approved randomized clinical trial or prospective comparative study	 CMS acknowledged it rarely completes NCDs for drugs or biologics, typically because 2 RCTs have already been completed before FDA approval. However, because of the implications for Medicare (elderly population with a higher prevalence of Alzheimer's Disease), CMS could not block coverage outright but still wanted to provide safeguards for patients in light of limited, inconclusive evidence.
	ICER	5 August 2021	Not recommended for coverage at the current price	Suggested 85–95% discount of list price for cost-effectiveness of aducanumab	 Judged current evidence to be insufficient to show a net health benefit for patients with mild cognitive impairments or mild Alzheimer's disease. ICER noted further analysis showing that the benefits of therapy are limited, and there are clear signs the therapy may harm patients instead. Recommendation to avoid using terms such as "improvement" or "return of quality of life" due to insufficient clinical benefit.
	NICE	N/A	Assessment suspended	Assessment suspended	Assessment suspended due to European authorities recommending refusal of the marketing authorization for aducanumab.
Plasma for chronic non-healing wounds	CMS	13 April 2021	Access, with restrictions	Coverage is granted for a maximum of 20 weeks of treatment for the management of exuding cutaneous wounds	 Utilized external and internal technology assessments to evaluate the effectiveness of the therapy. Outside of diabetic ulcers, there was insufficient conclusive evidence to support coverage. Local Medicare Administrative Contractors were provided authority to make additional coverage determinations as needed.
	ICER	N/A	N/A	N/A	N/A
	NICE	N/A	N/A	N/A	N/A
CAR T-cell therapies for cancers	CMS	7 August 2019	Access, with minor restrictions	Coverage was granted when therapies were administered at appropriate healthcare facilities	 Acknowledged ICER's prior assessment and critically assessed the results. The likelihood of severe AEs was a concern for treatment, but they were not substantially more likely than severe AEs with other existing therapies.
	ICER	23 March 2018	Recommended for coverage at the current price	No budget concerns were associated with tiagenlecleucel for B-ALL, but ICER estimated ~38% of individuals requiring axicabtagene ciloleucel for relapsed or refractory NHL could receive the therapy before budgetary thresholds were estimated to be crossed	 Judged current evidence to demonstrate moderate certainty of a small to substantial net health benefit for both therapies, compared to existing standard regimens. Cost-effectiveness for both therapies was below \$150,000 per QALY over a lifetime horizon.
	NICE	21 December 2018	Recommended under managed access	Can be used within the Cancer Drugs Fund for individuals with B-ALL aged up to 25 years, only if conditions in the specific managed access agreement are followed	 Clinical trial evidence suggests benefits for patients with B-ALL, but evidence is uncertain. Not enough evidence to determine costs of treating side effects. Most plausible cost-effectiveness estimates for tisagenlecleucel are higher than typical NICE thresholds. More data collection is necessary, and further evidence will be collected for re-evaluation in June 2023.

AE: adverse event; B-ALL: B-cell acute lymphoblastic leukemia; CAR: chimeric antigen receptor; CMS: Centers for Medicare and Medicaid Services; FDA: Food and Drug Administration; ICER: Institute for Clinical and Economic Review; N/A: not applicable; NCD: national coverage decision; NHL: non-Hodgkin's lymphoma; NICE: National Institute for Health and Care Excellence; QALY: quality-adjusted life year; RCT: randomized controlled trial.

Summary of coverage decisions by organization Medical therapy CMS ICER NICE Anti-amyloid-beta monoclonal antibodies N/A Plasma for chronic non-healing wounds N/A N/A

Clinical and Economic Review; N/A: not applicable; NICE: National Institute for Health and Care Excellence.

CAR: chimeric antigen receptor; CMS: Centers for Medicare and Medicaid Services; ICER: Institute for

CONCLUSIONS

therapies for cancers

CAR T-cell

- Since 2017, CMS has published few NCDs, with only a minority of NCDs applicable for medicinal products. Overall, CMS coverage decisions were consistent with the views of health technology assessment groups.
- It is noteworthy that aducanumab was the only medical product within the past six years to receive a negative coverage decision from CMS, though this is in line with similar recommendations from ICER.
- There was limited published information on how the factors evaluated by CMS influenced their decisions.
- Further research should be conducted to understand the trade-offs made by CMS when making NCDs; however, with the recent passage of the Inflation Reduction Act, it remains to be seen whether NCDs and local coverage patterns change now that CMS has the ability to negotiate drug prices directly with manufacturers.²

References

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