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Cost-effectiveness of daratumumab in multiple myeloma treatment: A systematic review

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ABSTRACT

Introduction: The cost-effectiveness of daratumumab in multiple myeloma treatment is a considerable criterion in clinical practice with tight health budgets. This review aimed to evaluate the cost-effectiveness of daratumumab in the treatment of multiple myeloma. Methods: The systematic review method was conducted under the guidance of PRISMA, identifying through a literature search from 3 databases (Embase, PubMed, and Cochrane) with relevant keywords. Nine articles among 95 found articles, satisfying the inclusion criteria, were analyzed. All studies were conducted in the US and China between 2017 and 2021, assessing the cost-effectiveness of adding daratumumab to current regimens. Results: Most of the studies were from a payer perspective, with ICER of $30,893-$1,445,533/QALY. Daratumumab was found to be cost-effective in 2 studies and not cost-effective in comparison with regimens without daratumumab in 7 remaining studies. Conclusions: The systematic review evaluating the cost-effectiveness of daratumumab in multiple myeloma treatment recorded varied ICER results ranging from $30,893/QALY to $1,445,533/QALY with heterogeneous conclusions about cost-effectiveness, The US and China are the only setting countries. More similar studies in developing countries are required to fully evaluate the cost-effectiveness of daratumumab in the treatment of multiple myeloma.

Keywords: *systematic review, cost-effectiveness, daratumumab, multiple myeloma*

1. INTRODUCTION

Multiple myeloma is a hematological cancer, characterized by malignant proliferation of plasma cells that secrete monoclonal proteins in serum and urine. The current worldwide prevalence is 6 - 7 cases per 100,000 people per year. In recent years, targeted therapies including daratumumab have increasingly succeeded in controlling multiple myeloma and improving disease prognosis [1]. With its high cost and outstanding efficacy, the cost-effectiveness of daratumumab is a remarkable criterion when using drugs in clinical practice with increasingly tight health budgets. Worldwide, many studies evaluating the cost-effectiveness of daratumumab in treating multiple myeloma have been conducted in several countries with different results. This study presents an overview of systematic reviews of the cost-effectiveness of daratumumab in the treatment of multiple myeloma, thereby creating a basis for the consideration of using daratumumab in many countries around the world.

2. MATERIALS AND METHODS

2.1. Materials

Cost-effectiveness studies of daratumumab in the treatment of multiple myeloma.

2.2. Methods

The cost-effectiveness of daratumumab in the treatment of multiple myeloma, as assessed by a systematic review with the PICOS research questions, is presented in Table 1.

Table 1. Research questions according to PICOS

P (Population)	Patients with multiple myeloma
I (Intervention)	Daratumumab
C (Comparator)	Other treatments
O (Outcome)	Indicators for economic evaluation
S (Study)	Economic evaluation studies

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A systematic review was performed according to PRISMA guidelines with the following steps: search and select research, data extraction and synthesis, and research quality evaluation. All steps were independently conducted by two researchers. In the event of a disagreement, a discussion was taken between the two researchers and a third participant to decide the problem and find a common solution.

2.2.1. Search and select studies

This research conducted a search until 30 August 2021 on e-library data sources, including Embase, PubMed, and Cochrane, to collect data on daratumumab's cost-effectiveness studies in the treatment of multiple myeloma. Search commands based on the following keywords: "cost-effectiveness", "cost-benefit", "cost-utility", "cost minimization", "daratumumab", "darzalex", "multiple myeloma", and the AND, OR operators.

The studies found were selected through the following selection criteria:

Inclusion criteria: Include studies that focus on cost-effectiveness analysis of daratumumab in the treatment of multiple myeloma. Additionally, the studies are written in English.

Exclusion criteria: Studies will be excluded if the full text is not available. In addition, certain types of publications will not be considered, including system overviews, letters to the editorial board, case reports, commentaries, and clinical trials

2.2.2. Extract, synthesize, and present data

Information was extracted including study characteristics (author name, country, year of study, population, perspective, currency), study design (study model and model characteristics, timing, outcome measurement method, discount rate, cost reference date), and study outcome (interventions and comparisons, clinical outcome, cost outcome, total cost, ICER values, conclusions regarding cost-effectiveness, sensitivity analysis). The results were converted to the same currency (USD in 2020) based on the consumer price index (CPI) and the foreign exchange rate [2] by the following formula:

$$ICER_{2020} = ICER_{year\ of\ study} * (CPI_{2020} / CPI_{year\ of\ study}) * \text{Exchange rate}$$

2.2.3. Evaluation of research quality

We used the CHEERS (Consolidated Health Economic Evaluation Reporting Standards) checklist [3] to evaluate the quality of the studies. The CHEERS checklist [3], consists of 24 criteria. For each content, the study was scored as follows: 0 - not mentioned, 1 - with full mention, 0.5 - is mentioned but is incomplete or does not meet the specified content of the checklist.

3. RESULTS AND DISCUSSIONS

3.1. Search and select research

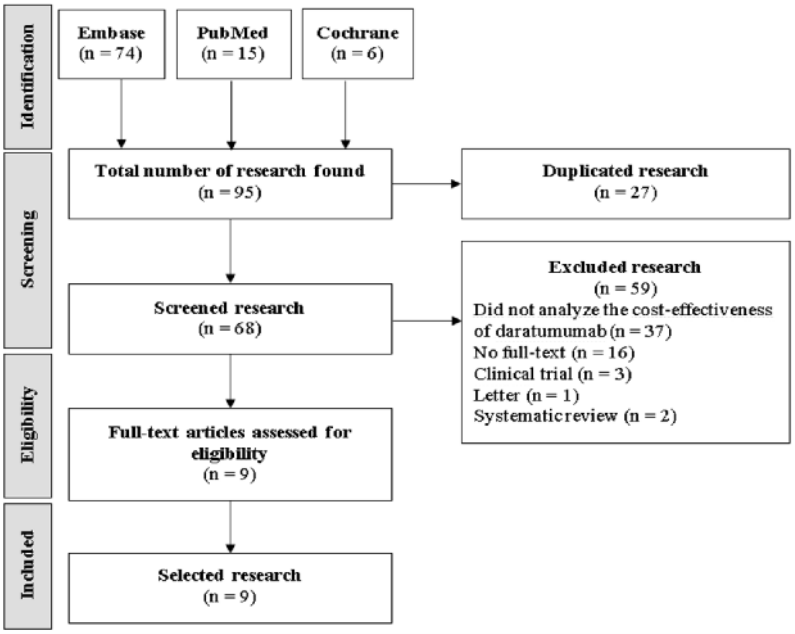

Figure 1. PRISMA flowchart

Based on the search commands on 3 databases, we found 95 research articles (74 articles from Embase, 15 articles from PubMed, 6 articles from Cochrane). After removing the duplication (27 articles) and screening according to inclusion criteria, we obtained 68 related studies. According to the exclusion criterion, the study eliminated 59 articles, of which 37 articles did not analyze the cost-effectiveness of daratumumab; 16 were no full-text articles; 3 were clinical trials; 1 letter and a systematic review. The remaining 9 studies were continued to be included in the systematic analysis. The research selection scheme is shown in Figure 1.

3.2. Evaluation of research quality

Details of the criteria are shown in Table 5 in the Appendix 2. Summary results are presented in Table 2.

Table 2. Evaluation of research quality

RESEARCH	Christoper G.Pelligra et al. (2017) [4]	Tian-tian Zhang et al. (2018) [5]	Josh J.Carlson et al. (2018) [6]	Cynthia L.Gong et al. (2019) [7]	Xiaohui Zeng et al.(2020) [8]	Kishan K.Patel et al. (2021) [9]	Xiaohui Zeng et al. (2021) [10]	SiNi Li et al. (2021) [11]	Yaohua Cao et al. (2021) [12]
TOTAL SCORE	22	22	21	16.5	20.5	20.5	21	23	23

According to Table 2, the quality score ranged from 16.5 to 23 with the highest score of 23 belonging to the study of Li S et al. 2021) [11] and Yaohua Cao (2021) [12], the lowest score of 16.5 for the study of Cynthia L.Gong (2019) [7]. The sections that lose points in studies consist of abstract [7]; target population and subgroups [7, 10]; setting and location [8, 9]; discount rate [7]; measurement of effectiveness: single study-based estimates [4 - 6, 8, 9, 12]; measurement of effectiveness [7, 10, 11]; estimating resources and costs [4 - 6, 8, 9, 12]; estimating resources and costs: model-based economic evaluation [7, 10, 11]; analytical methods [9]; characterising uncertainty for single study-based economic evaluation [4 - 6, 8, 9, 12]; characterising uncertainty for model-based economic evaluation [7, 10, 11]; characterising heterogeneity [4 - 12]; study findings, limitations, generalisability, and current knowledge [10]; conflicts of interest [6].

3.3. Characteristics of studies

The characteristics of the 9 selected studies are summarized in Table 3.

Table 3. Summary of selected studies' characteristics

Author (year of study)	Nation	Perspective	Study design	Time horizon	Type of cost, effectiveness	Discount for cost and effectiveness	Sensitivity analysis
Christopher G.Pelligra et al. (2017) [4]	US	Payer	Model	3 years	Direct cost; QALYs a, LYs	3%	Deterministic and probabilistic
Tian-tian Zhang et al. (2018) [5]	US	Payer	Markov model	10 years	Direct cost; QALYs	3%	Deterministic, one-way, and probabilistic
Josh J. Carlson et al. (2018) [6]	US	Health system	Partition survival model	Lifetime	Direct cost; QALYs	3%	Deterministic and one-way
Cynthia L. Gong et al. (2019) [7]	US	Payer	Markov model	Lifetime	Direct cost; QALYs	-	One-way and probabilistic

Author (year of study)	Nation	Perspective	Study design	Time horizon	Type of cost, effectiveness	Discount for cost and effectiveness	Sensitivity analysis
Xiaohui Zeng et al. (2020) [8]	US	Payer	Markov model	Lifetime	Direct cost; QALYs, LYs	3%	Univariate and probabilistic
Kishan K Patel et al. (2021) [9]	US	Payer	Markov model	Lifetime	Direct cost; QALYs	3%	Probabilistic, one-way, and scenario analyses
Xiaohui Zeng et al. (2021) [10]	China	Health system	Markov model	Lifetime	Direct cost; QALYs, LYs	3%	One-way and probabilistic
SiNi Li et al. (2021) [11]	US	Payer	Markov model	Lifetime	Direct cost; QALYs, LYs	3%	One-way and probabilistic
Yaohua Cao et al. (2021) [12]	US	Payer	Markov model	Lifetime	Direct cost; QALYs, LYs	3%	Deterministic, one-way and probabilistic

Note: QALYs: Quality Adjusted Life Years, LYs: life-years gained

According to Table 3, 8 studies were conducted in the US[4 - 9, 11, 12], and 1 study was conducted in China [10] from 2017 to 2021 in patients with multiple myeloma who did not respond to treatment or have a recurrence, patients who did not qualify for transplantation. Most studies (7 out of 9 studies) were from the payer perspective [4, 5, 7 - 9, 11, 12], and only 2 from the health system perspective [6, 10]. 7 studies used the Markov model [5, 7 - 12] and 1 study used the partition survival model [6]. Time horizon varied between studies, from 3 years[4] to the patient's lifetime[6 - 12] with cycles from 1 week to 4 weeks. Direct costs (including medical and non-medical) were assessed in all articles. Regarding the efficiency index, all studies used QALYs (Quality Adjusted Life Years), of which 5 studies used the LYGs (life-years gained - years of life gained) in addition [4, 8, 10 - 12]. A discount was applied to both cost and efficiency, with a value of 3% in all studies. All studies performed a sensitivity analysis to assess model uncertainty with a variety of methods, such as deterministic sensitivity analysis, one-way analysis, univariate analysis, probability analysis, and situational analysis.

3.4. The results of the studies

The ICERs conversion is presented in Table 4.

Table 4. The results of the studies

Author (Year)	Intervention	ICER/QALY (Research year)	ICER/QALY (2021)	Willingness to pay (WTP)	Conclusion
Christopher G.Pelligra et al. (2017) [4]	DAR vs POM-d	POM-d dominated DAR		$50.000/QALY	DAR was not cost-effective compared to POM-d
Tian-tianZhang et al. (2018) [5]	DAR + LEN + DEX vs LEN + DEX	$284.180	$300.053	$50.000/QALY	Two combinations with DAR were not cost-effective compared with 2 combinations without DAR
	DAR + BOR + DEX vs BOR + DEX	$1.369.062	$1.445.533		

Author (Year)	Intervention		ICER/QALY (Research year)	ICER/QALY (2021)	Willingness to pay (WTP)	Conclusion
Josh J. Carlson et al. (2018) [6]	Second-line	DAR+ LEN+ DEX vs LEN+ DEX	$187.728	$202.436	$150.000/QALY	The addition of DAR to the BOR + DEX regimen was considered cost-effective compared to LEN + DEX
		DAR+BOR+ DEX vs LEN + DEX	$50.704	$54.676		
	Third-line	DAR + LEN + DEX vs LEN + DEX	$216.360	$233.311		
		DAR + BOR + DEX vs LEN + DEX	$60.359	$65.088		
Cynthia L. Gong et al. (2019) [7]	DAR vs POM		$156.385	$165.120	$160.000/QALY	DAR was cost-effective relative to POM
Xiaohui Zeng (2020) et al. [8]	DAR+ BOR+ DEX vs BOR+ DEX		$213.164 $163.184/LYG	$219.704 $168.190/LYG	$200.000/QALY	The combination with DAR was not cost-effective compared with the combination without DAR
Kishan K Patel et al. (2021) [9]	DAR first-line vs DAR second-line		$618.018	$618.018	$150.000/QALY	First-line use of DAR was not cost-effective compared with second-line use of DAR
Xiaohui Zeng et al. (2021) [10]	D-VMP vs VMP		$116.015 $64.920/LYG	$117.446 $65.720/LYG	$30.950/QALY	D-VMP versus VMP is likely to exceed the commonly accepted values of cost-effectiveness

Note: DAR: Daratumumab, BOR: Bortezomib; LEN: Lenalidomide; DEX: Dexamethasone; POM-d: Pomalidomide + low-dose dexamethasone; POM: Pomalidomide; D-VMP: Daratumumab + Bortezomib + Melphalan + Prednisone; VMP: Bortezomib + Melphalan + Prednisone, WTP: Willingness to pay.

According to Table 4, the systematic review found six studies evaluating the cost- effectiveness between combinations with daratumumab such as DAR + LEN + DEX, DAR + BOR + DEX, D-VMP, and combinations without daratumumab such as LEN + DEX, BOR + DEX, VMP [5, 6, 8, 10 - 12]. Only two studies evaluated the cost-effectiveness between daratumumab monotherapy and other treat-ments such as POM or POM-d [4, 7], and one study evaluated the cost-effectiveness between daratumumab first-line and second-line [9]. The ICER of the DAR + LEN + DEX combination compared with LEN + DEX in the study by Tian-tian Zhang (2018) [5] was $300,053/QALY, which was higher

than that in the study by Josh J. Carlson (2018) [6] $202,436/QALY for second-line and $233,311/QALY for third-line. Similarly, the study by Tian-tian Zhang (2018) [5] also showed that the ICER of the DAR + BOR + DEX combination compared to BOR + DEX was much higher than the study by Xiaohui Zeng (2020) [8] ($1,445,533/QALY and $219,704/QALY). Yaohua Cao (2021) [12] noted that the ICER of the D-VMP combination compared to VMP was $388,364/QALY and $262,526/LYG, which was much higher than that in the study by Xiaohui Zeng (2021) [10] ($117,446/QALY and $65,720/LYG) and the study by Li S et al. (2021) [11] ($30,893 and $18,995/LYG). The study by Christopher G.Pelligra (2017) [4] noted that the POM-d therapy dominated daratumumab monotherapy, and the study by Cynthia L. Gong (2019) [7] noted that the ICER of daratumumab monotherapy compared with POM was $165,120/QALY. The study by Kishan K Patel (2021) [9] indicated that the ICER of first-line use of daratumumab compared to the second-line was $618,018/QALY.

A systematic review found that neither the addition of daratumumab to LEN + DEX nor the BOR + DEX regimen proved to be cost-effective under US WTP, according to the studies of Tian-tian Zhang (2018) [5], J. Carlson (2018) [6] and Xiaohui Zeng (2020) [8]. However, the study of Josh J. Carlson (2018) [6] found that the DAR + BOR+ DEX combination was cost-effective compared with the LEN + DEX. Yaohua Cao (2021) [12] concluded that the addition of daratumumab to the VMP regimen was not cost-effective compared to VMP under US WTP of $150,000/QALY, yet this contrasts with the findings by Li S et al. (2021) [11]. Similarly, the study by Xiaohui Zeng (2021) [10] reached the same conclusion as the study by Yaohua Cao (2021) [12] under China WTP. In the cost-effectiveness evaluation of daratumumab monotherapy, the study by Christopher G.Pelligra (2017) [4] concluding that POM-d was a cost-effective option which dominated daratumumab monotherapy under WTP of $50,000/QALY, but the study of Cynthia L. Gong (2019) [7] showed that at the higher WTP ($160,000/QALY), daratumumab was cost-effective relative to POM. The study by Kishan K Patel (2021) [9] also indicated that second-line use of daratumumab was more cost-effective than first-line. Moreover, the systematic review also noted a significant variation in the ICERs of all related studies, fluctuating from to $30,893/QALY to $1,445,533/QALY. The lowest ICER belongs to the study by Josh J. Carlson (2018) [6], while research by Tian-tian Zhang (2018) [5] recorded the highest ICER.

4. DISCUSSION

Based on inclusion and exclusion criteria, nine eligible studies were included in the systematic review. The selected studies were rated good quality according to the CHEERS checklist, and they were conducted in the US and China from a payer perspective and health system perspective. All studies analyzed direct medical costs and applied a 3% discount rate. The results of the studies were mainly based on the ICER/QALY, though some studies by Christopher G. Pelligra (2017) [4], Xiaohui Zeng (2020) [8], Xiaohui Zeng (2021) [10], SiNi Li (2021) [11] and Yaohua Cao (2021) [12] also added an ICER/LYG index.

This systematic review reports that daratumumab was not cost-effective compared with standard regimens in the treatment of multiple myeloma. Among a total of nine records were identified, seven of them showed that the addition of daratumumab to standard regimens was likely to exceed the commonly accepted values of cost-effectiveness. There is only two research showed that daratumumab was cost-effective, including the study by Li S et al. (2021) [11] and the study by Cynthia. L Gong (2018) [7].

Currently, all studies have mainly been conducted in developed countries such as the US, China. There is no research conducted in developing countries. Therefore, the cost-effectiveness evidence of daratumumab needs to be proven effectively in developing countries with limited resources.

There is a remarkable difference in the ICER between studies. This difference can be explained by the interventions of different drug combinations, the use of dissimilar assumptions and follow-up periods. In addition, the difference in study perspective also affected the final result, as all studies from the payer perspective concluded that daratumumab was not cost-effective, in contrast to the study by Josh J. Carlson (2018) [6] with the health system's perspective. Most studies showed that combinations with daratumumab, such as DAR + LEN + DEX, DAR + BOR + DEX, and D-VMP, were not cost-effective compared with combinations without daratumumab, such as LEN + DEX, BOR. + DEX and VMP. Only Josh J. Carlson (2018) [6] concluded that the combination of DAR + BOR + DEX was cost-effective compared with the LEN + DEX combination but not cost-effective compared with the BOR + DEX combination in both second-line and third-line. This can be explained

because the cost for LEN + DEX is higher than the cost for BOR + DEX. In the study by Josh J. Carlson (2018) [6], the cost of second-line and third-line treatment for LEN + DEX are $309,997 and $281,754, which is almost double the cost for BOR + DEX ($189,357 and $175,315). Moreover, there are three studies evaluating the cost-effectiveness between D-VMP combination and the VMP combination, in which two studies of Xiaohui Zeng (2021) [10] and Yaohua Cao (2021) [12] concluded that D-VMP was not cost-effective compared with VMP. However, the study of Li S et al. (2021) [11] came to the opposite conclusion. When comparing two studies of Xiaohui Zeng [10] and Li S et al. [11], it can be seen that the study of Li S et al. was conducted in the US, which has a higher willingness to pay (WTP) than the study of Xiaohui Zeng conducted in China. This may lead to the conclusion of Xiaohui Zeng that D-VMP was not cost-effective compared to VMP in China. For the two studies of SiNi Li [11] and Yaohua Cao [12], although both were performed in the US with similar willingness to pay (WTP), SiNi Li performed with a 6-week cycle time, and Yaohua Cao performed with a 4-week cycle. This may be the reason for the difference in the conclusions of the two studies. Furthermore, this systematic review identified two studies comparing daratumumab (DAR) monotherapy with pomalidomide (POM) monotherapy and pomalidomide + low-dose dexamethasone (POM-d) combination. These two studies showed that daratumumab monotherapy was cost-effective compared to POM but not cost-effective compared to POM-d, additionally, POM-d outperformed daratumumab monotherapy in terms of cost-effectiveness, even with a low willingness to pay (WTP) ($50,000). This suggests that the addition of low-dose dexamethasone with pomalidomide may show benefits both in terms of cost as well as effectiveness compared with daratumumab alone.

To our knowledge, currently there are two systematic reviews evaluating the cost-effectiveness of daratumumab in multiple myeloma treatment in the world (Sarah Perry (2019) [13] and Ziyan Chen (2021) [14]). The study by Sarah Perry (2019) [13] has 2 studies related to daratumumab (Christopher G. Pelligra (2017) [4] and Tian-tianZhang (2018) [5]), and the study by Ziyan Chen (2021) [14] has only one study related to daratumumab (Christopher G. Pelligra (2017) [4]). These studies recorded the same results as our systematic review. This is possibly because daratumumab has just recently been approved by the FDA in 2015 [1]. Therefore, our systematic review is fully up to date. However, our systematic review has a few limitations. Inclusion, exclusion criteria, as well as follow-up time, may also affect the final result and limit the comparison between studies. Firstly, the data source is limited to only 3 databases, including Embase, PubMed, Cochrane. Secondly, language bias may occur because of language barriers, as we only searched among English publications. Finally, the studies in this review were quite heterogeneous in terms of economic model, study perspective, and study population, which will also influence their generalizability.

5. CONCLUSION

The systematic review evaluating the cost-effectiveness of daratumumab in multiple myeloma treatment recorded varied ICER results ranging from $30,893/QALY to $1,445,533/QALY with heterogeneous conclusions about cost-effectiveness, The US and China are the only settings countries. Therefore, more research on the cost-effectiveness of daratumumab in the treatment for multiple myeloma needs to be conducted, especially in developing countries.

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Tổng quan hệ thống chi phí - hiệu quả của daratumumab trong điều trị đa u tủy

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TÓM TẮT

Giới thiệu: Hiệu quả chi phí của daratumumab trong điều trị đa u tủy là một tiêu chí quan trọng trong thực hành lâm sàng với ngân sách y tế hạn hẹp. Bài tổng quan này nhằm đánh giá hiệu quả chi phí của daratumumab trong điều trị đa u tủy. Phương pháp: Phương pháp đánh giá có hệ thống được thực hiện theo hướng dẫn của PRISMA, với việc tìm kiếm tài liệu từ 3 cơ sở dữ liệu (Embase, PubMed và Cochrane) bằng các từ khóa liên quan. Chín bài báo trong số 95 bài tìm được, thỏa mãn tiêu chí đưa vào, đã được phân tích. Tất cả các nghiên cứu được thực hiện tại Mỹ và Trung Quốc trong giai đoạn từ 2017 đến 2021, đánh giá hiệu quả chi phí của việc thêm daratumumab vào các phác đồ điều trị hiện tại. Kết quả: Hầu hết các nghiên cứu được thực hiện từ góc nhìn của nhà chi trả với ICER dao động từ $30,893 đến $1,445,533/QALY. Daratumumab được tìm thấy có hiệu quả chi phí trong 2 nghiên cứu, và không hiệu quả chi phí so với các phác đồ không có daratumumab trong 7 nghiên cứu còn lại. Kết luận: Đánh giá có hệ thống về hiệu quả chi phí của daratumumab trong điều trị đa u tủy ghi nhận các kết quả ICER khác nhau, dao động từ $30,893/QALY đến $1,445,533/QALY với các kết luận không đồng nhất về hiệu quả chi phí, trong đó Mỹ và Trung Quốc là hai quốc gia duy nhất. Cần có thêm nhiều nghiên cứu tương tự ở các quốc gia đang phát triển để đánh giá đầy đủ hiệu quả chi phí của daratumumab trong điều trị đa u tủy.

***Từ khóa**: đánh giá có hệ thống, hiệu quả chi phí, daratumumab, đa u tủy*

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