



# DIETA ELIMINACYJNA PKU COOLER® W FENYLOKETONURII

**ANALIZA EKONOMICZNA**

Wersja 1.0

**Wykonawca:**

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Warszawa, 11 kwietnia 2013 r.

Autorzy	Wykonywane zadania
[REDACTED]	<ul style="list-style-type: none"><li>• Koncepcja analizy;</li><li>• Kontrola jakości</li><li>• Modelowanie;</li><li>• Wnioski i dyskusja</li></ul>
[REDACTED]	<ul style="list-style-type: none"><li>• Opracowanie wyników;</li><li>• Identyfikacja i opracowanie ograniczeń analizy;</li><li>• Gromadzenie i opracowanie danych wejściowych do modelu;</li><li>• Przegląd systematyczny do jakości życia i innych analiz ekonomicznych;</li><li>• Modelowanie;</li><li>• Wnioski i dyskusja;</li><li>• Analiza wrażliwości</li></ul>
[REDACTED]	<ul style="list-style-type: none"><li>• Przegląd systematyczny badań do oceny jakości życia i innych analiz ekonomicznych</li></ul>

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**Konflikt interesów:**

Raport wykonano na zlecenie Nestle Polska S.A., która finansowała pracę.

Autorzy nie mieli innego rodzaju konfliktu interesów.

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## Indeks skrótów

Skrót	Objaśnienie
AOTM	Agencja Oceny Technologii Medycznych
CCA	ang. <i>cost-consequences analysis</i> – analiza kosztów-konsekwencji
CEAR	ang. <i>Cost-Effectiveness Analysis Registry</i> – baza danych dotyczących analiz kosztów-efektywności
CHB	cena hurtowa brutto
CRD	ang. <i>Centre for Reviews and Dissemination</i> – Centrum Przeglądów i Rozpowszechniania brytyjskiej służby zdrowia
█	██
█	██
█	██
█	██
MZ	Minister Zdrowia
NFZ	Narodowy Fundusz Zdrowia
Phe	ang. <i>phenylalanine</i> – fenyloalanina
PKB	Produkt Krajowy Brutto
PKU	ang. <i>phenylketonuria</i> – fenyloketonuria
█	██
█	██
QoL	ang. <i>quality of life</i> – jakość życia
WHO	ang. <i>World Health Organization</i> – Światowa Organizacja Zdrowia

## Streszczenie

### CEL I ZAKRES ANALIZY

Celem analizy była ocena opłacalności stosowania w Polsce diety eliminacyjnej PKU Cooler® w fenylketonurii. Analiza dotyczy trzech prezentacji środka spożywczego dostępnego w czterech różnych smakach (white, orange, purple, red): PKU Cooler® (30x87 ml), PKU Cooler® (30x130 ml) oraz PKU Cooler® (30x174 ml). Dobór komparatorów oparto na przeprowadzonej *Analizie klinicznej*.

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### METODYKA

W celu oceny opłacalności stosowania produktu PKU Cooler® we wskazanej populacji chorych, [REDACTED]

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## 1. Cel i zakres analizy ekonomicznej

Analiza została przygotowana w celu oceny opłacalności stosowania w Polsce diety eliminacyjnej PKU Cooler® w fenylketonurii.

Doboru komparatorów dokonano w oparciu o *Analizę kliniczną* [11].

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## 2. Strategia analityczna

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### 3. Perspektywa

Leczenie chorych na fenylketonurię w Polsce współfinansowane jest z budżetu płatnika publicznego. Ponadto, ze względu na odpłatność ryczałtową diet eliminacyjnych pacjent partycypuje w kosztach związanych z leczeniem fenylketonurii w Polsce. Z tego względu analizę ekonomiczną wykonano z perspektywy wspólnej (płatnika publicznego i pacjenta) oraz z perspektywy płatnika publicznego.

### 4. Horyzont czasowy

Zgodnie w Wytycznymi Agencji Oceny Technologii Medycznych (AOTM) horyzont czasowy analizy ekonomicznej powinien być wystarczająco długi, aby możliwa była ocena różnic między wynikami i kosztami ocenianej technologii medycznej oraz komparatorów. W przypadku technologii medycznych, których wyniki i koszty ujawniają się w ciągu całego życia chorego, horyzont czasowy powinien zamykać się w momencie zgonu pacjenta [1].

### 5. Dyskontowanie

W decyzji odnośnie do finansowania danej technologii medycznej należy uwzględnić koszty i efekty kliniczne jakie będzie ona generowała w określonym horyzoncie



czasowym. Zgodnie z teorią ekonomii, wartości przyszłe ponoszonych kosztów (i uzyskiwanych efektów zdrowotnych) nie są równe wartościom kosztów (ani uzyskiwanym efektom zdrowotnym) ponoszonych w chwili obecnej. W celu uniknięcia błędów, wartości przyszłe należy wyrazić w wartościach teraźniejszych, czemu służy dyskontowanie.

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## 6. Ocena wyników zdrowotnych

### 6.1. Skuteczność kliniczna

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## 6.2. Profil bezpieczeństwa

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## 6.3. Jakość życia

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## 7. Technika analityczna

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Zgodnie z Wytycznymi Agencji Oceny Technologii Medycznych (AOTM) [1], przeprowadzono także analizę **kosztów i konsekwencji** (CCA, ang. *cost-consequences analysis*).

## 8. Analiza kosztów

W analizie uwzględniono koszty odpowiadające zużyciu zasobów w praktyce klinicznej w Polsce. Wszystkie różnice w kosztach ujawniają się w przyjętym dla analizy horyzoncie czasowym i są ponoszone przez płatnika publicznego oraz pacjenta.

W niniejszej analizie brano pod uwagę następujące koszty medyczne bezpośrednie, różniące oceniane technologie medyczne:

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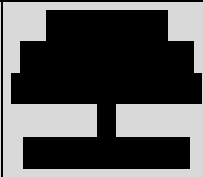
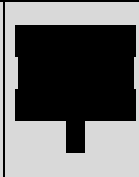

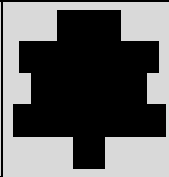






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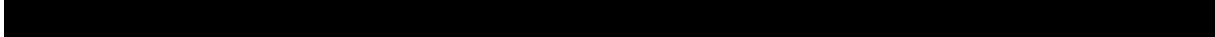

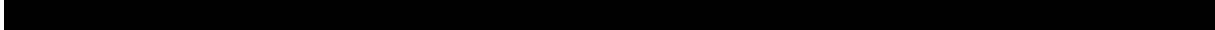
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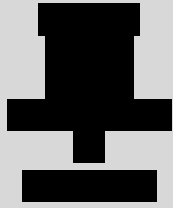


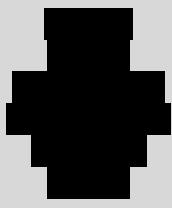
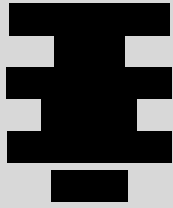
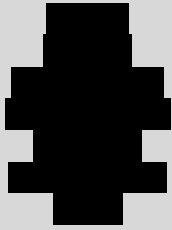
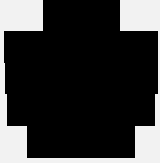
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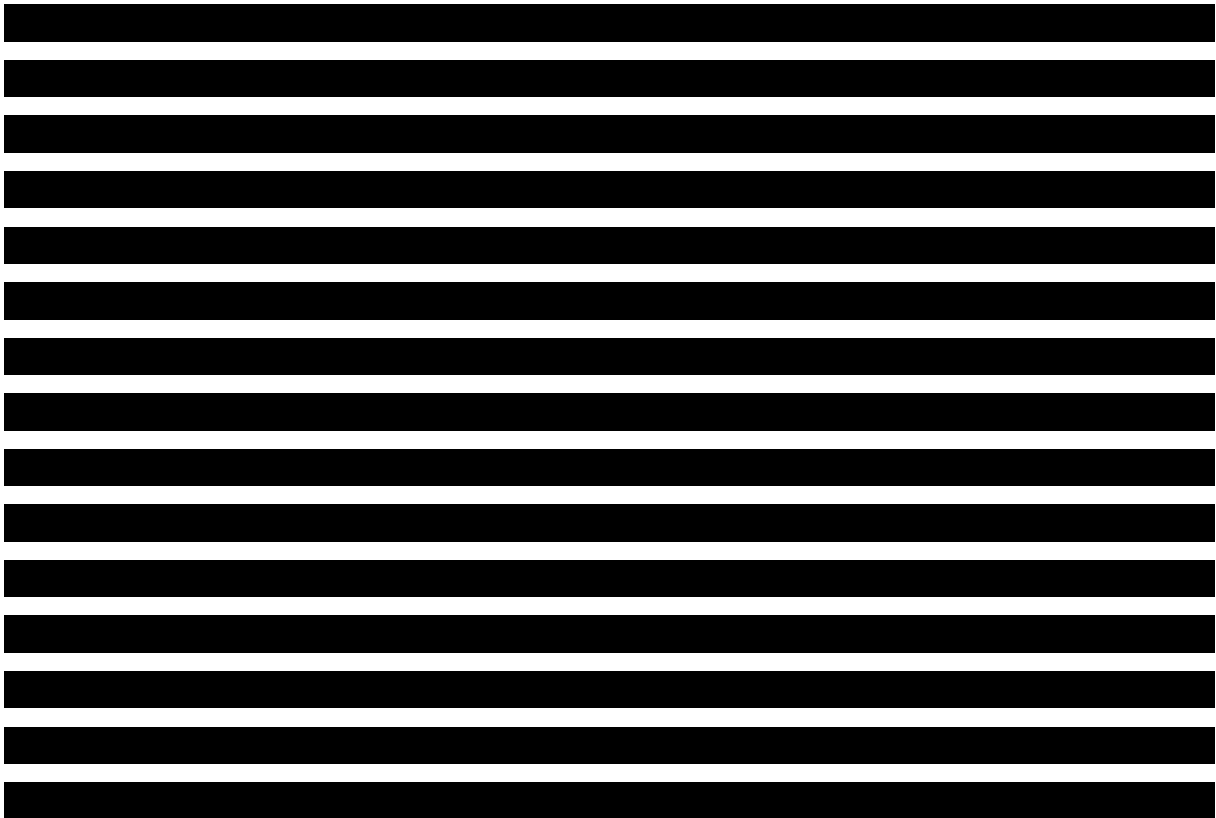
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## 9. Modelowanie

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## 10. Walidacja modelu

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## 11. Przedstawienie wyników

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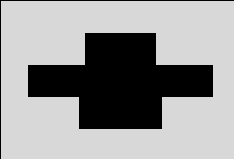





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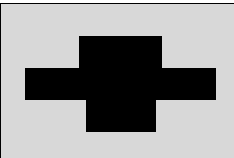
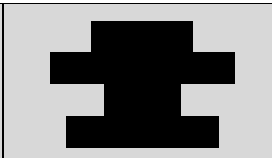
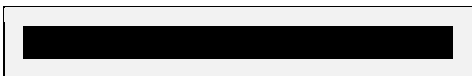

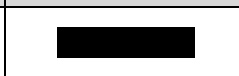
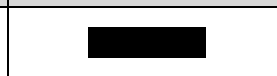
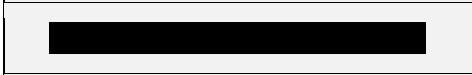



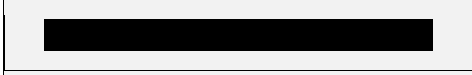

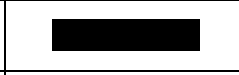
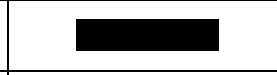
















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## 13. Analiza progowa

Zgodnie z *Rozporządzeniem Ministra Zdrowia z dnia 2 kwietnia 2012 r. w sprawie minimalnych wymagań, jakie muszą spełniać analizy uwzględnione we wnioskach o objęcie refundacją i ustalenie urzędowej ceny zbytu oraz o podwyższenie urzędowej ceny zbytu leku, środka spożywczego specjalnego przeznaczenia żywieniowego, wyrobu medycznego, które nie mają odpowiednika refundowanego w danym wskazaniu* [55] (zwanym dalej *Rozporządzeniem w sprawie minimalnych wymagań*) analiza ekonomiczna powinna zawierać oszacowanie ceny zbytu netto wnioskowanej technologii, przy którym koszt uzyskania dodatkowego roku życia skorygowanego o jakość w wyniku zastąpienia technologii opcjonalnych wnioskowaną, jest równy wysokości progu określonego na podstawie *Ustawy z dnia 12 maja 2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych* [62] (zwana dalej *Ustawą o refundacji*). Próg ten (nazywany dalej zamiennie progiem opłacalności) zdefiniowano jako trzykrotność Produktu Krajowego Brutto (PKB) na jednego mieszkańca (w rozumieniu *Ustawy z dnia 26 października 2000 r. o sposobie obliczania wartości rocznego produktu krajowego brutto* [60]). Określono, że zgodnie z *Obwieszczeniem Prezesa Głównego Urzędu Statystycznego z dnia 31 października 2012 r. w sprawie szacunków wartości produktu krajowego brutto na jednego mieszkańca w latach 2008—2010* [29] PKB per capita wyniosło w Polsce 35 267 PLN (lata 2008-2010), a tym samym wysokość progu opłacalności wynosi w Polsce obecnie **105 801 PLN**.

### 13.1. Perspektywa wspólna



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Nazwa produktu	Cena		Wartość			
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### 13.2. Perspektywa płatnika publicznego

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#### 14. Wielokierunkowa analiza wrażliwości

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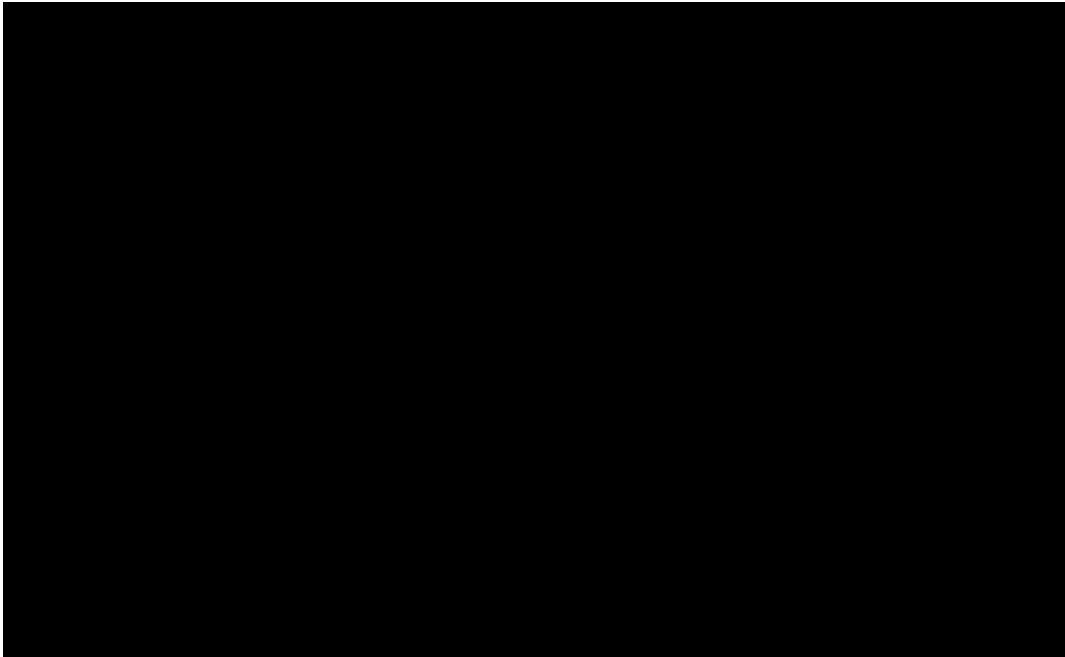
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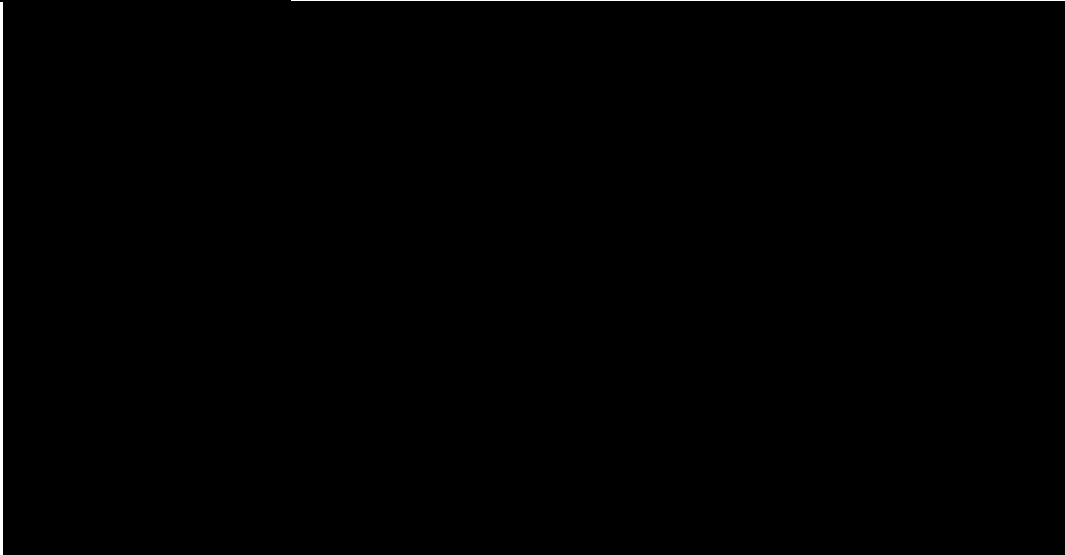
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## **15. Obszary rozbieżności między częścią kliniczną a kosztową**

### **15.1. Sposób prezentacji efektu zdrowotnego**

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[REDACTED]

## 15.2. Prezentacja zdarzeń w czasie

[REDACTED]

## 15.3. Zakres danych wykorzystywanych do przedstawienia wyników

[REDACTED]

## 16. Ograniczenia i założenia

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## 18. Podsumowanie i wnioski końcowe

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## 19. Załączniki

### 19.1. Przegląd systematyczny badań do oceny jakości życia chorych na fenylketonurię

Oprócz wyników zdrowotnych z badań klinicznych, w modelu konieczne było również określenie jakości życia chorych w analizowanym wskazaniu. Z tego względu w niniejszej analizie wykonano przegląd systematyczny, mający na celu odnalezienie badań do oceny jakości życia chorych.

#### 19.1.1. Kryteria włączenia i wykluczenia badań do oceny jakości życia chorych

Do analizy ekonomicznej były włączane badania spełniające poniżej zdefiniowane kryteria, które zostały ustanowione *a priori* w protokole do przeglądu systematycznego.

##### Kryteria włączenia badań:

- [REDACTED]
- [REDACTED]

##### Kryteria wykluczenia badań:

- [REDACTED]
- [REDACTED]

### 19.1.2. Strategia wyszukiwania

W celu odnalezienia badań do oceny jakości życia chorych zastosowano strategie wyszukiwania. Strategie zastosowane do przeszukania bazy Embase i Medline ( [REDACTED] ) oraz Cochrane Library zaprezentowano poniżej. Strategie te zawierają terminy odnoszące się do wyżej zdefiniowanych kryteriów włączenia badań.

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
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Dodatkowo, przeszukano bazę *Cost-Effectiveness Registry* (CEAR). Słowa kluczowe zastosowane do przeszukania tych baz zaprezentowano poniżej.

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### 19.1.3. Selekcja badań

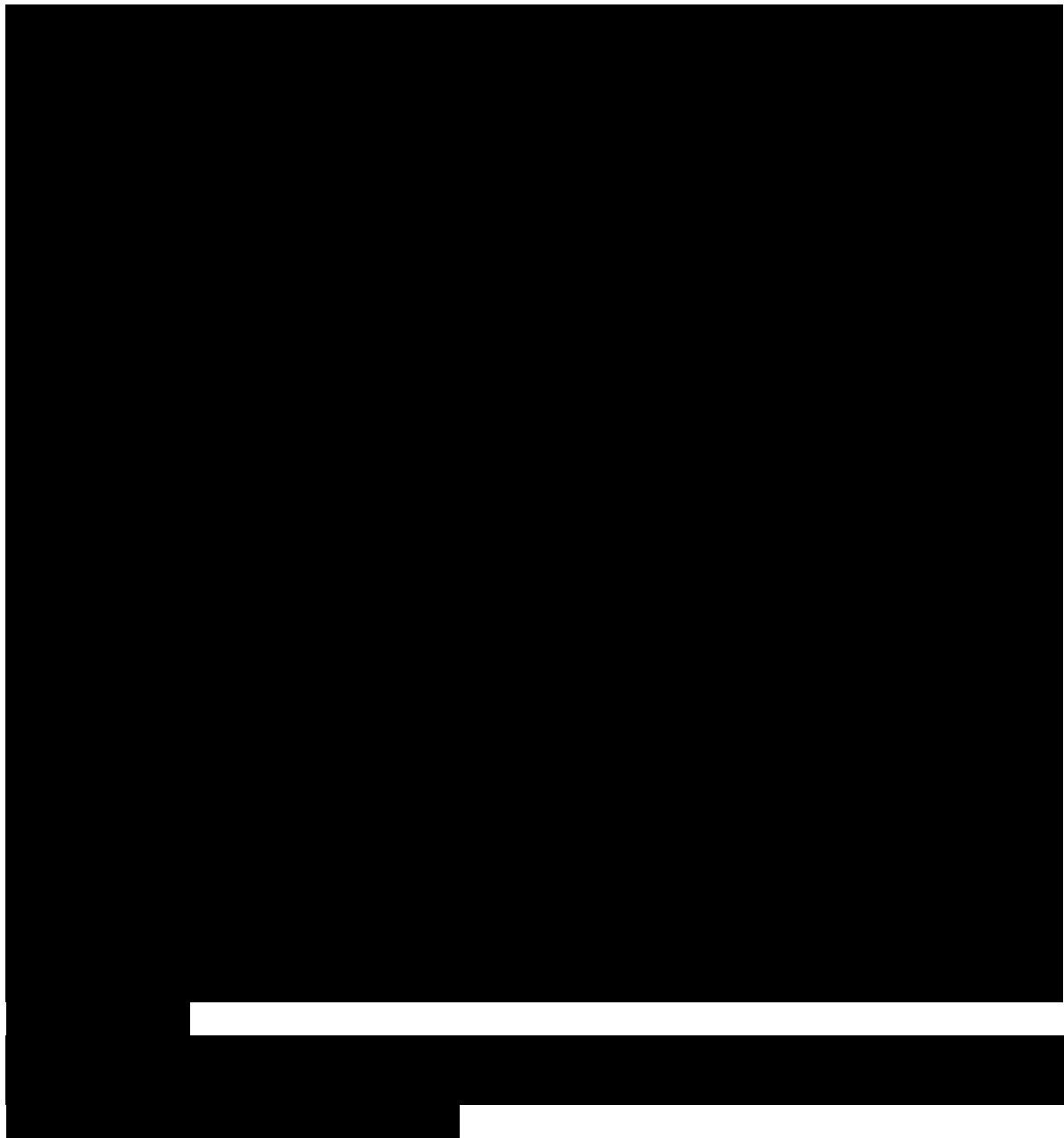
Odnalezione publikacje w głównych bazach medycznych Medline, Embase i Cochrane Library oraz bazie dodatkowej (CEAR) zostały poddane selekcji na podstawie tytułów i streszczeń, a następnie pełnych tekstów. [REDACTED]

[REDACTED]


[REDACTED]

Selekcję oparto na wcześniej zdefiniowanych kryteriach włączenia i wykluczenia, opisanych w rozdziale 19.1.1.

Proces selekcji badań do oceny jakości życia zobrazowano na diagramie, przedstawionym poniżej.



#### **19.1.4. Publikacje do oceny jakości życia chorych odnalezione na podstawie przeglądu systematycznego i włączone do analizy**

W wyniku przeszukiwania głównych baz informacji medycznej (Medline, Embase, Cochrane Library) odnaleziono 

Ponadto przeszukano:

- *Cost-Effectiveness Analysis Registry*, w której odnaleziono [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

#### 19.1.5. Metodyka włączonych badań do oceny jakości życia chorych

[REDACTED]  
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

## 19.2. Przegląd systematyczny innych analiz ekonomicznych wykonanych w Polsce lub za granicą

### 19.2.1. Kryteria włączenia i wykluczenia innych analiz ekonomicznych

Do analizy ekonomicznej zostały włączone badania spełniające poniżej zdefiniowane kryteria, które zostały ustanowione *a priori* w protokole do przeglądu systematycznego.

#### Kryteria włączenia badań:

- [REDACTED]

- [REDACTED]
- [REDACTED]  
[REDACTED]
- [REDACTED]  
[REDACTED]

**Kryteria wykluczenia badań:**

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

**19.2.2. Strategia wyszukiwania**

W celu odnalezienia innych analiz ekonomicznych zastosowano strategie wyszukiwania. Strategie zastosowane do przeszukania bazy Embase i Medline ([REDACTED]) oraz Cochrane Library zaprezentowano poniżej. Strategie te zawierają terminy odnoszące się do wyżej zdefiniowanych kryteriów włączenia badań.

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]



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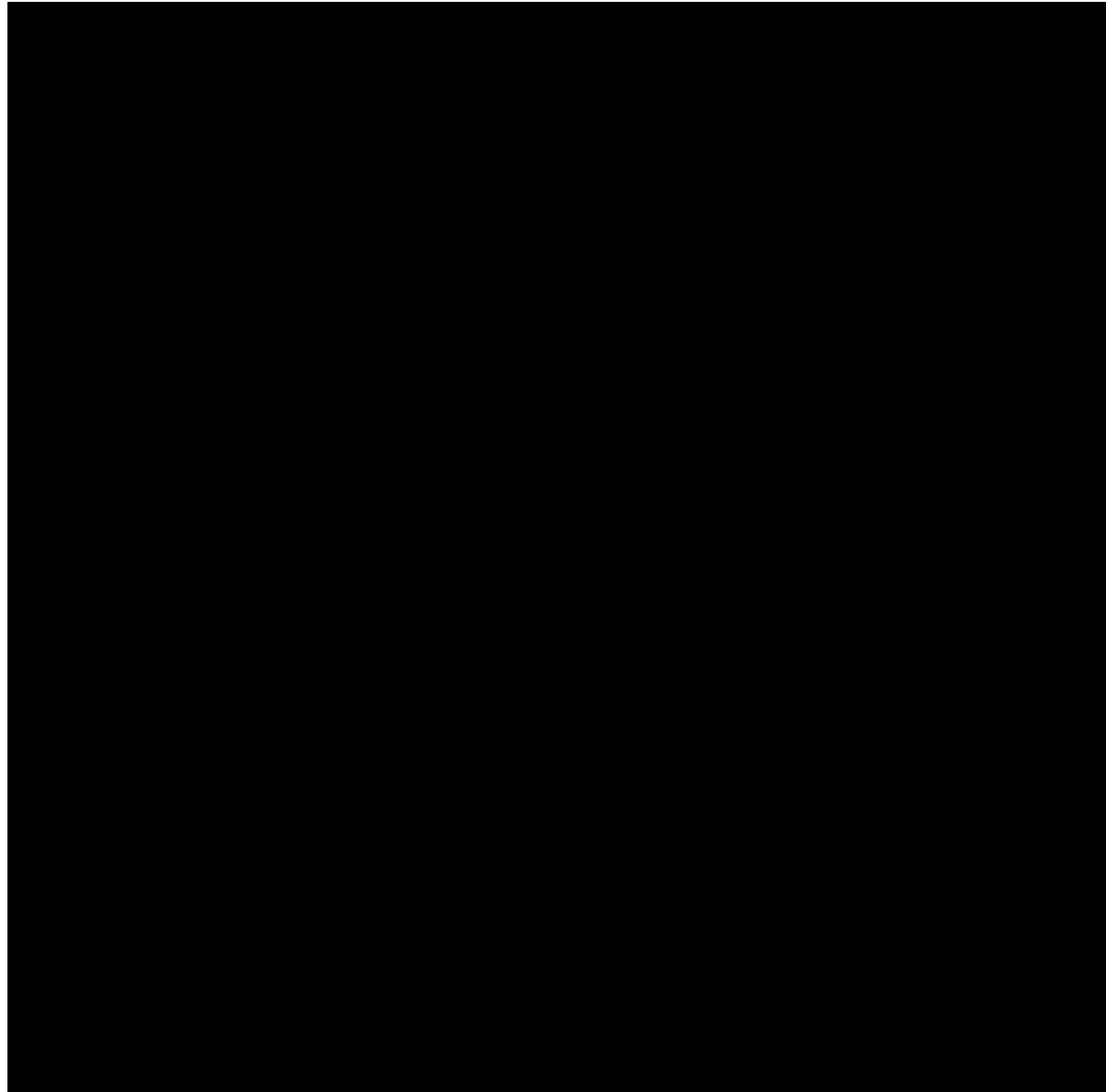
Dodatkowo, w analizie przeszukano bazę *Cost-Effectiveness Registry* (CEAR). W bazie tej, do odnalezienia innych analiz ekonomicznych, zastosowano słowa kluczowe związane z problemem zdrowotnym oraz stosowaną interwencją i komparatorami. Słowa kluczowe do przeszukania tej bazy zaprezentowano poniżej.

[REDACTED]

■	[REDACTED]	[REDACTED]
■	[REDACTED]	[REDACTED]
■	[REDACTED]	[REDACTED]
■	[REDACTED]	[REDACTED]
■	[REDACTED]	[REDACTED]
■	[REDACTED]	[REDACTED]
■	[REDACTED]	[REDACTED]
■	[REDACTED]	[REDACTED]
■	[REDACTED]	[REDACTED]



Selekcję oparto na wcześniej zdefiniowanych kryteriach włączenia i wykluczenia, opisanych w rozdziale 19.2.1.



Proces selekcji innych analiz ekonomicznych zobrazowano na diagramie, przedstawionym poniżej.



[REDACTED]

#### **19.2.4. Inne analizy ekonomiczne odnalezione na podstawie przeglądu systematycznego i włączone do niniejszej analizy**

W wyniku przeszukiwania głównych baz informacji medycznej (Medline, Embase, Cochrane Library) odnaleziono [REDACTED]

Ponadto przeszukano:

- *Cost-Effectiveness Analysis Registry*, w której odnaleziono [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

#### **19.2.5. Metodyka włączonych publikacji prezentujących wyniki innych analiz ekonomicznych**

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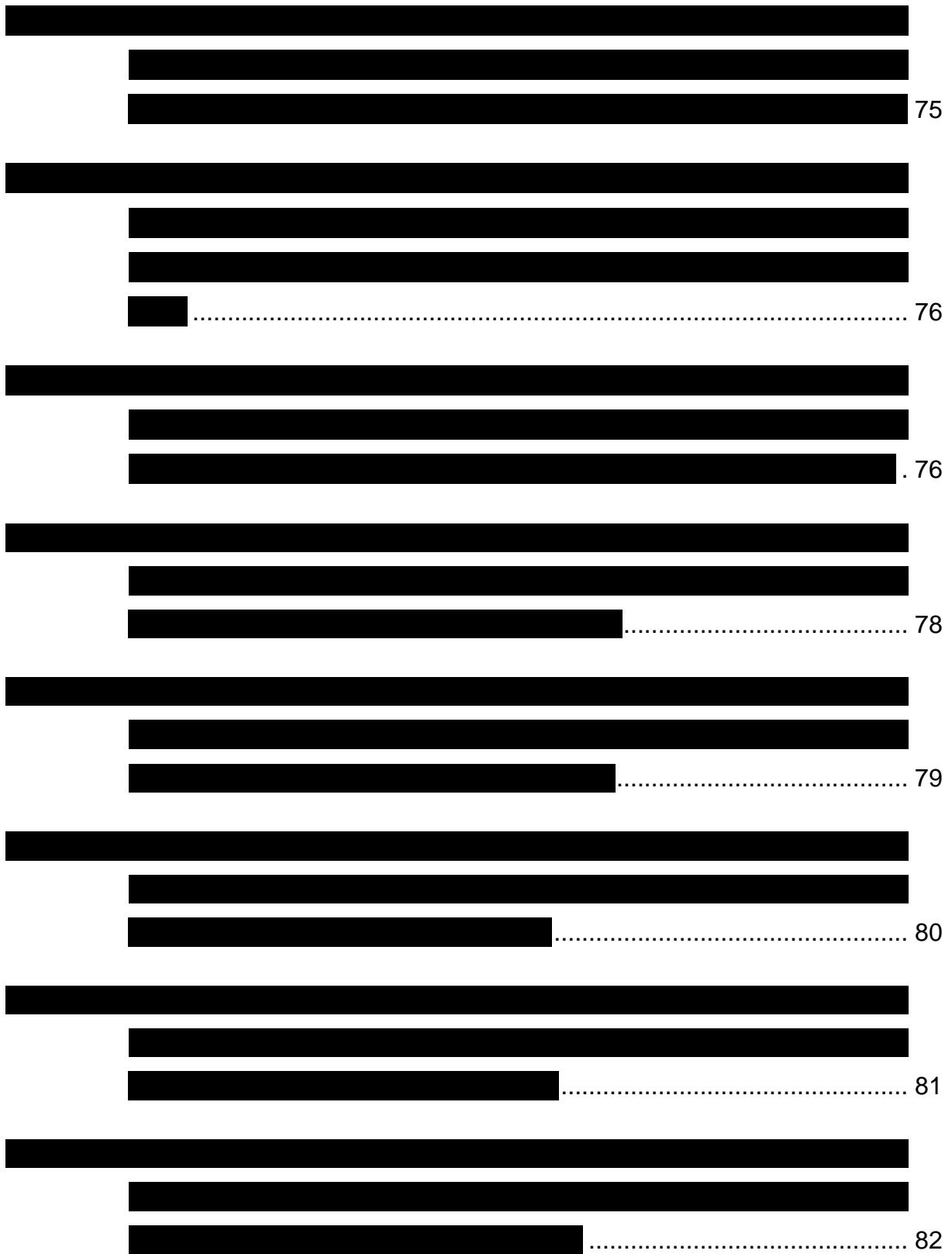


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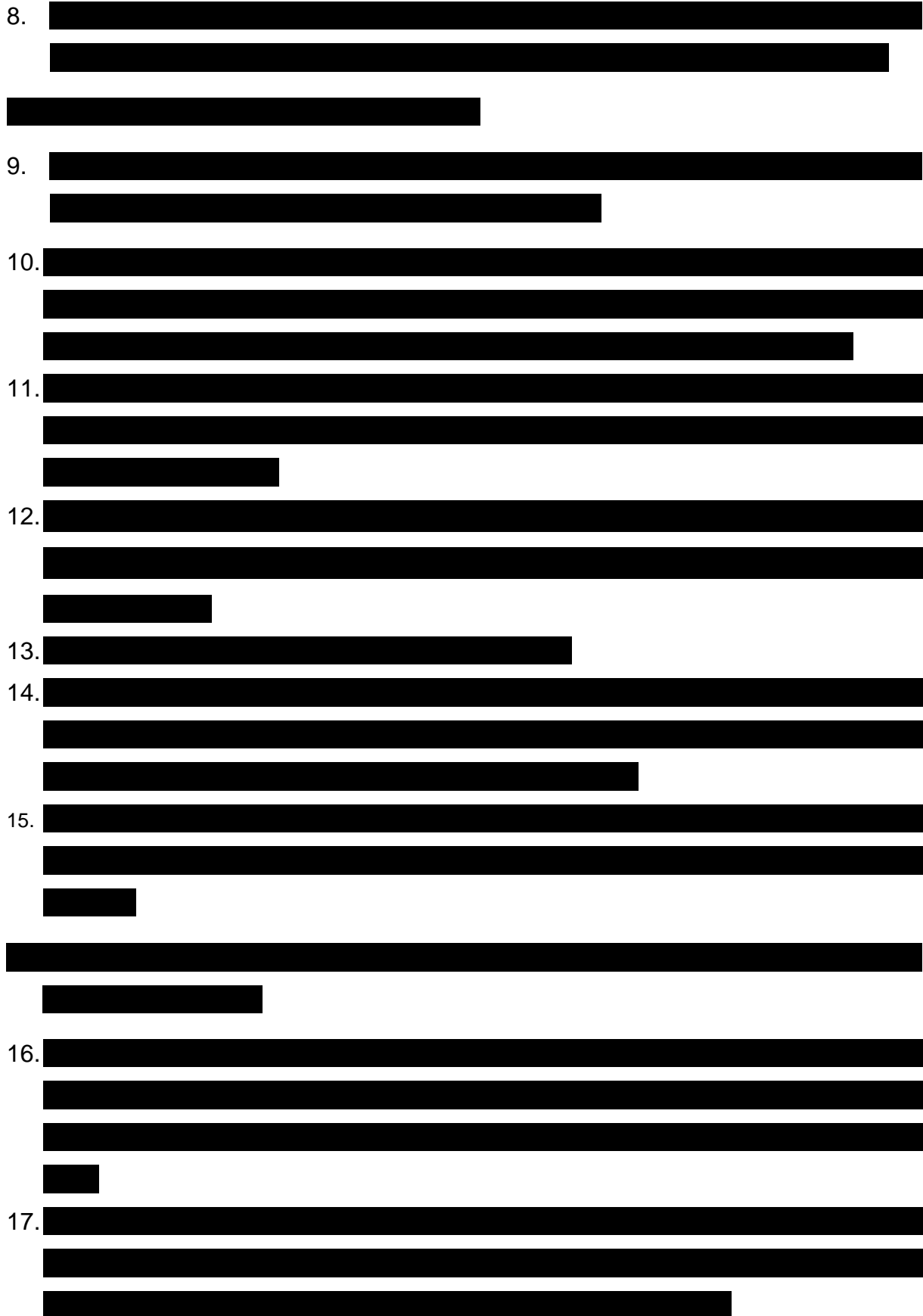
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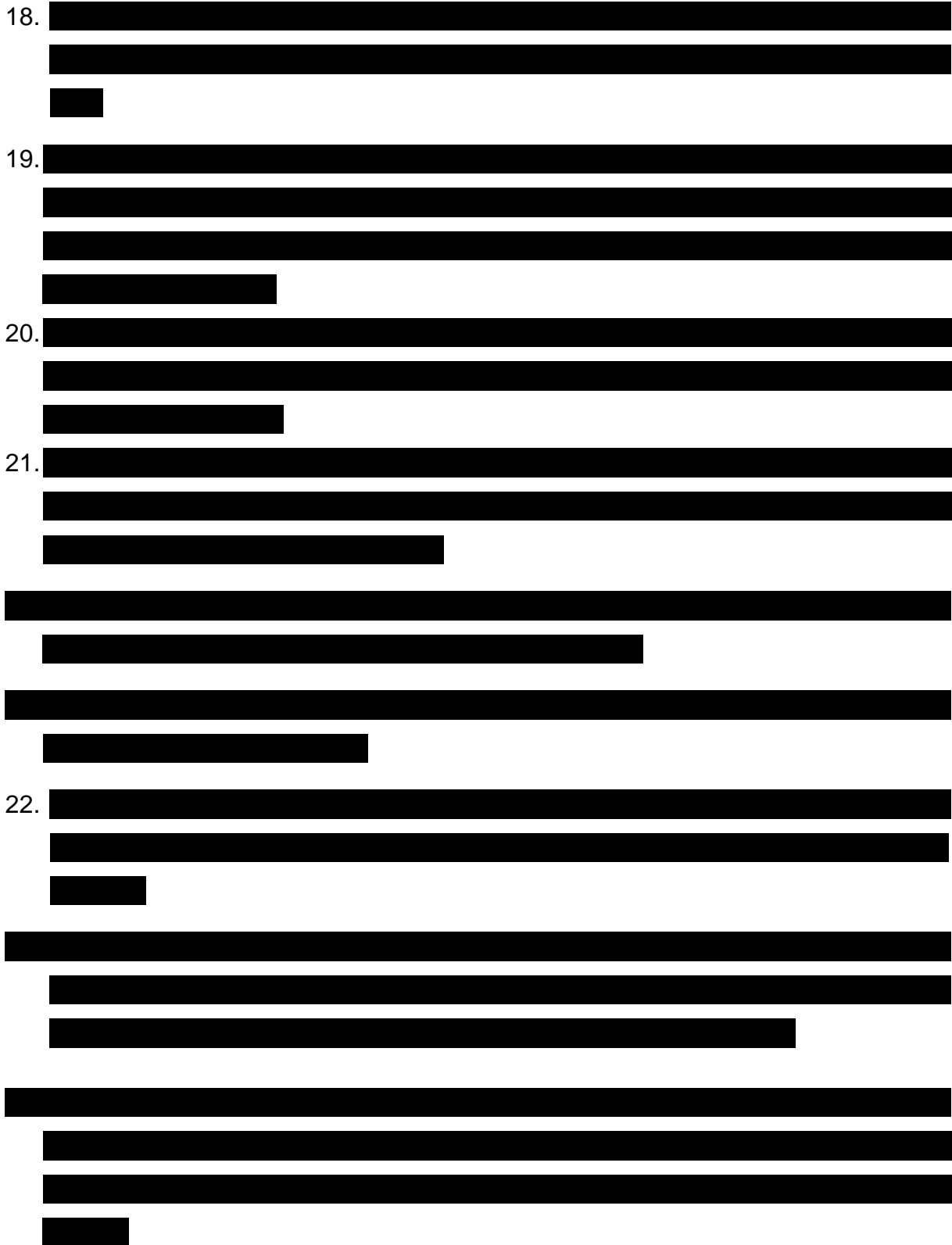
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## 22. Bibliografia

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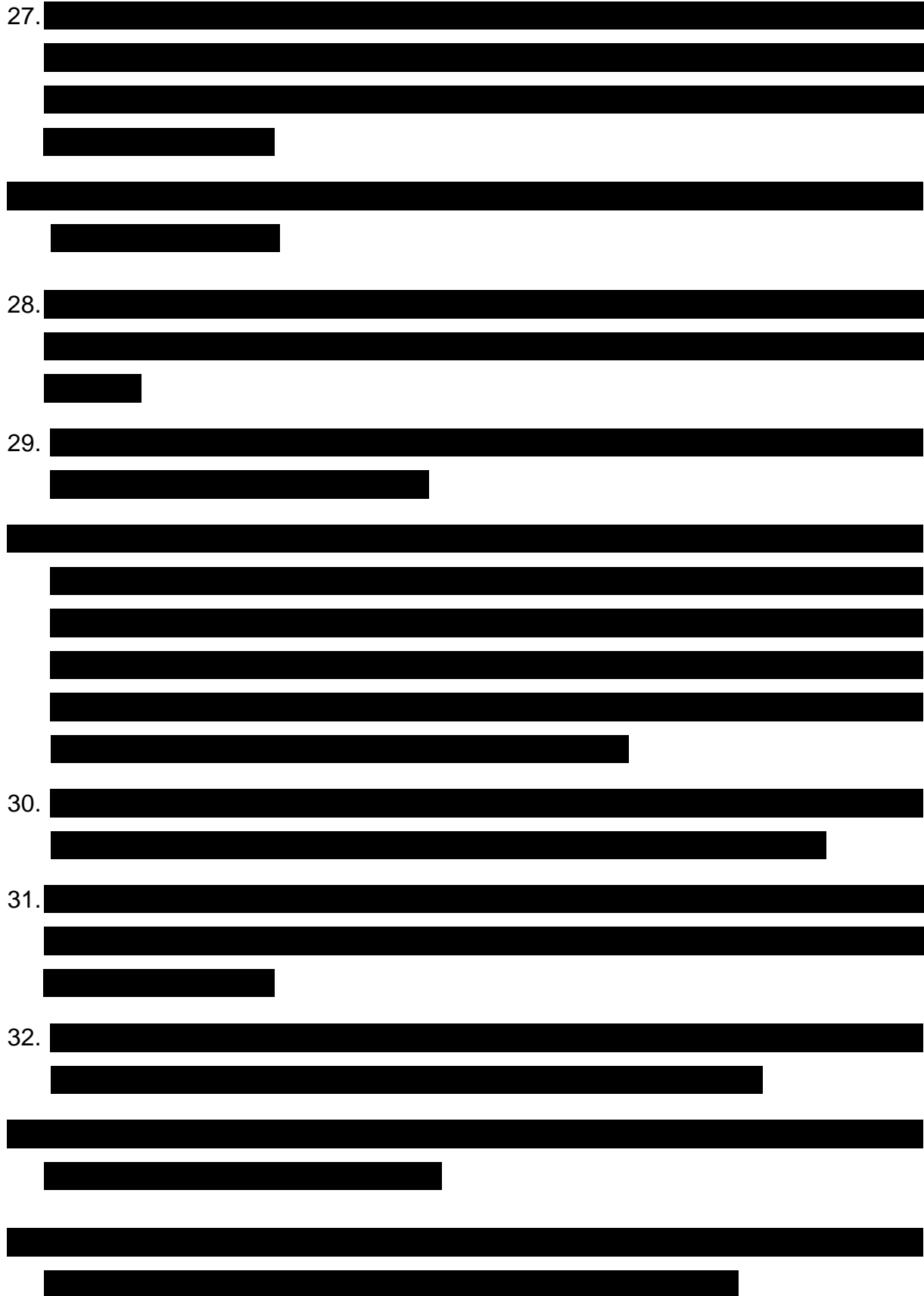
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