



# **DIETA ELIMINACYJNA PKU EXPRESS® 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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## Streszczenie

### CEL I ZAKRES ANALIZY

Celem analizy była ocena opłacalności stosowania w Polsce diety eliminacyjnej PKU Express® w fenylketonurii. Analiza dotyczy dwóch prezentacji środka spożywczego dostępnego w czterech różnych smakach (neutralny, tropikalny, pomarańczowy i cytrynowy): PKU Express® (30x25 g) oraz PKU Express® (30x34 g). Dobór komparatorów oparto na przeprowadzonej *Analizie klinicznej*.

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### METODYKA

W celu oceny opłacalności stosowania produktu PKU Express® 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 Express® w fenyloketonurii.

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

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[REDACTED]

## 2. Strategia analityczna

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## 3. Perspektywa

Leczenie chorych na fenyloketonurię w Polsce współfinansowane jest z budżetu płatnika publicznego. Ponadto, ze względu na odpłatność ryczałtową diet eliminacyjnych pacjent partycypuje w kosztach związanych z leczeniem fenyloketonurii 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].

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## 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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## 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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## 10. Walidacja modelu

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## 11. Przedstawienie wyników

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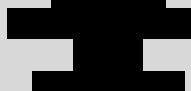
















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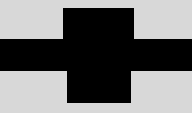
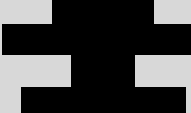








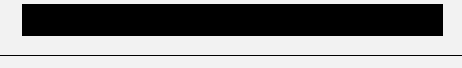







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## 12. Jednokierunkowa analiza wrażliwości

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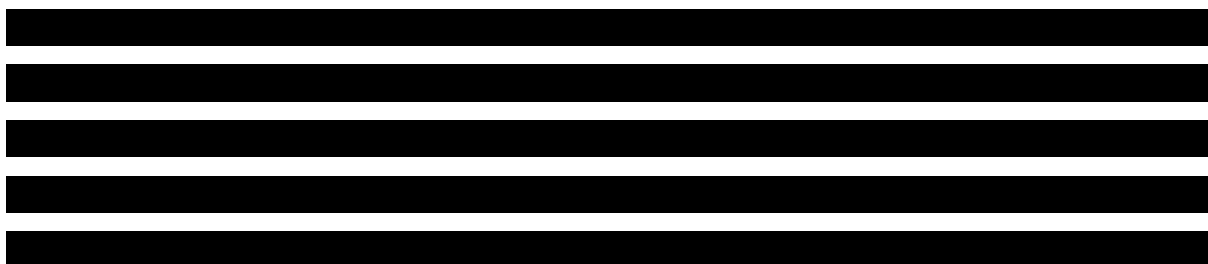
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## 13. Analiza progowa

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* [53] (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* [60] (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* [58]). 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* [27] 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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## 14. Wielokierunkowa analiza wrażliwości

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

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

[REDACTED]

[REDACTED]

### **15.2. Prezentacja zdarzeń w czasie**

[REDACTED]

### **15.3. Zakres danych wykorzystywanych do przedstawienia wyników**

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## 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 fenyloketonurię

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]



[REDACTED]

### 19.1.2. Strategia wyszukiwania

W celu odnalezienia badań do oceny jakości życia chorych zastosowano strategię 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.

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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. ██████████

██

██

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.

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#### **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 [REDACTED]

Ponadto przeszukano:

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

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

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## 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 strategię 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]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]







### 19.2.3. 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 19.2.1.

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

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#### **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]

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

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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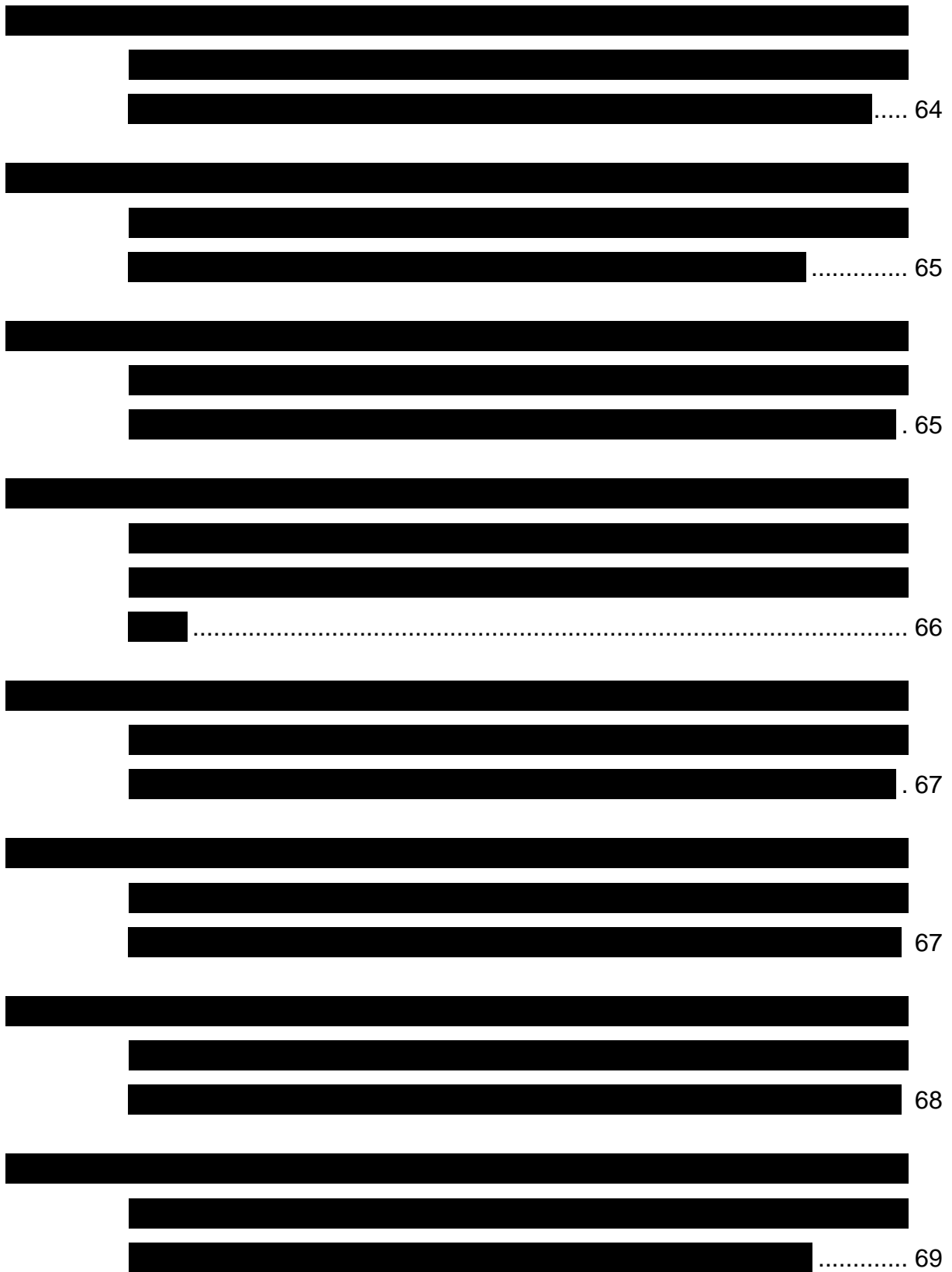
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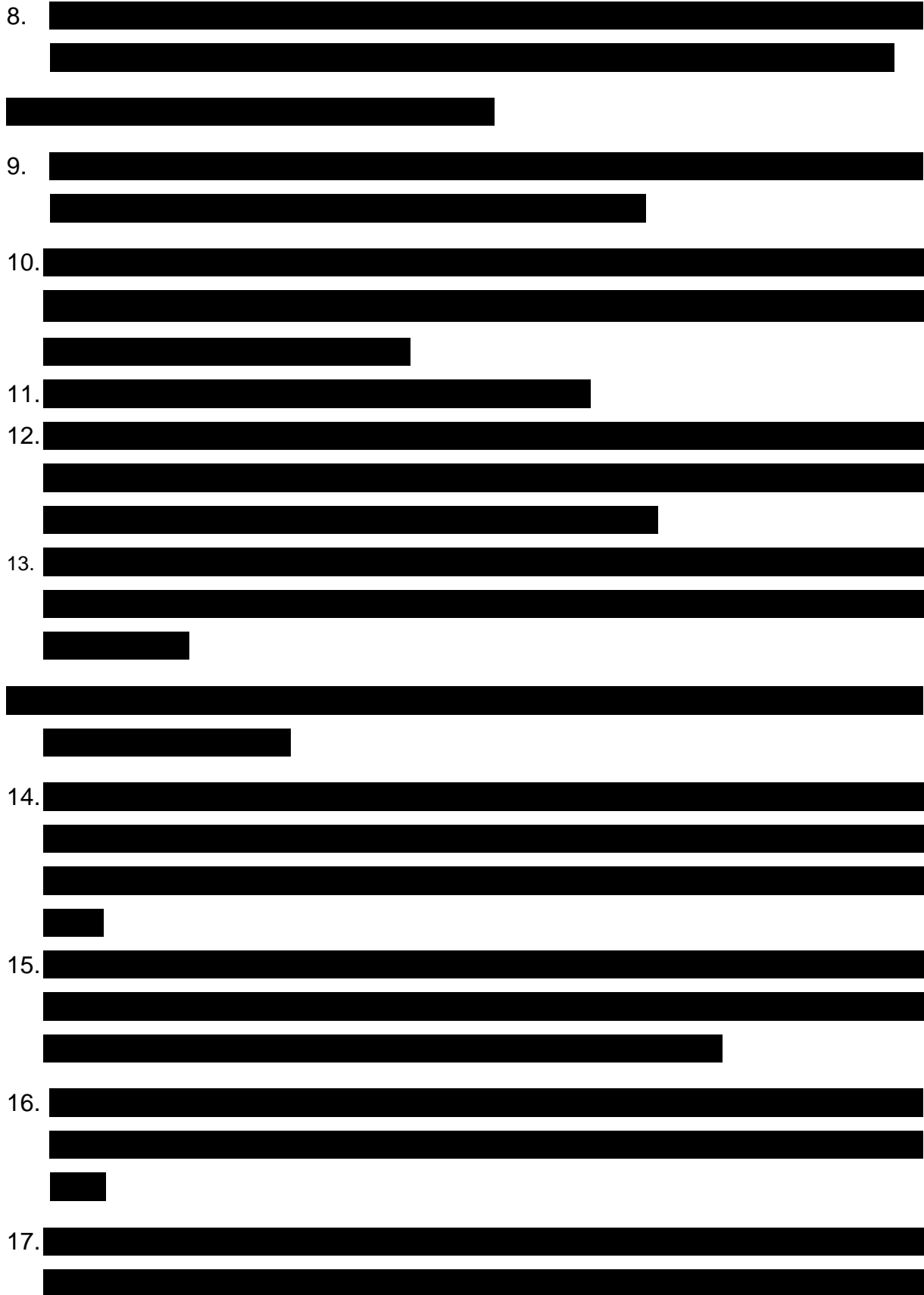
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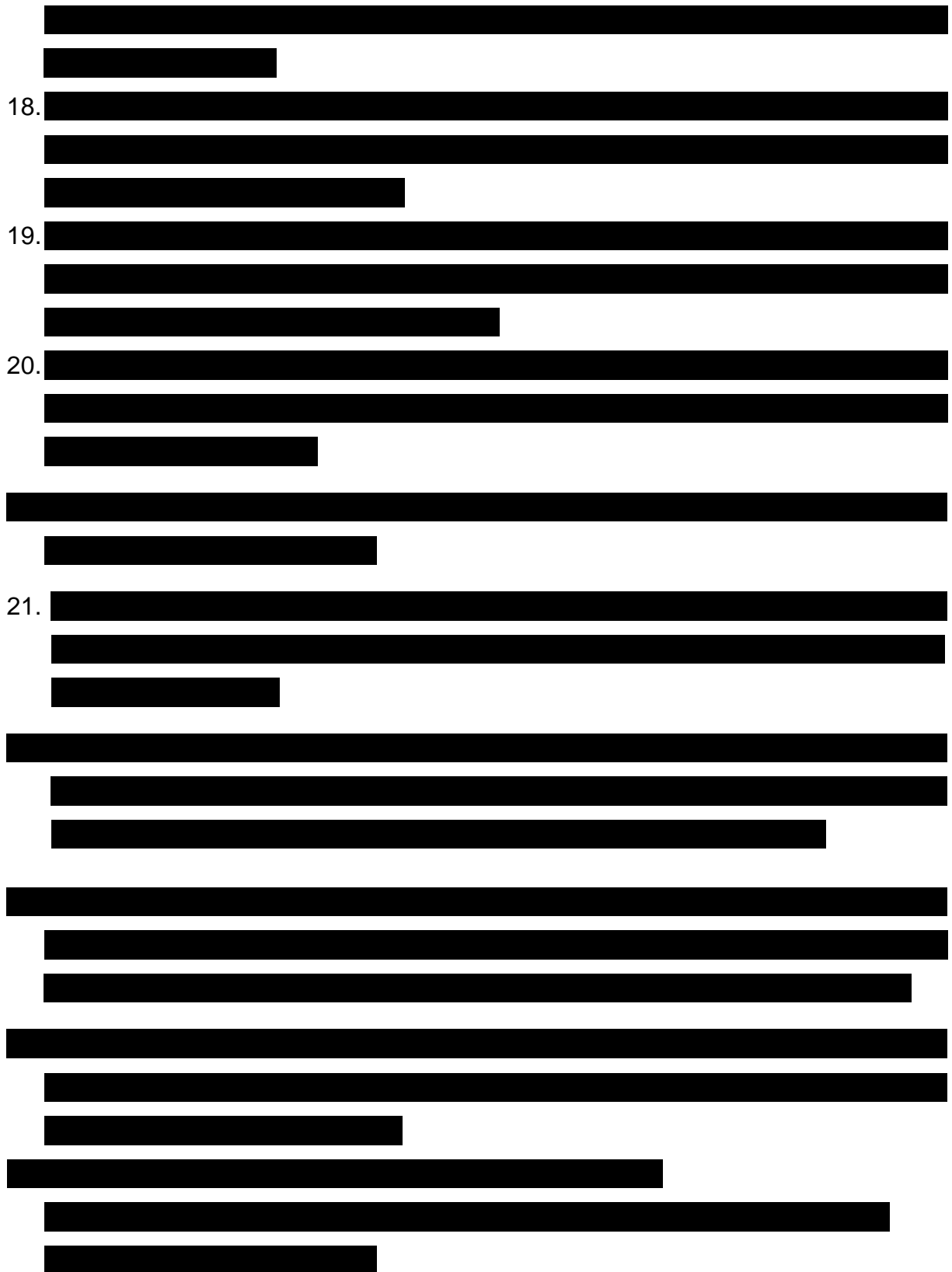
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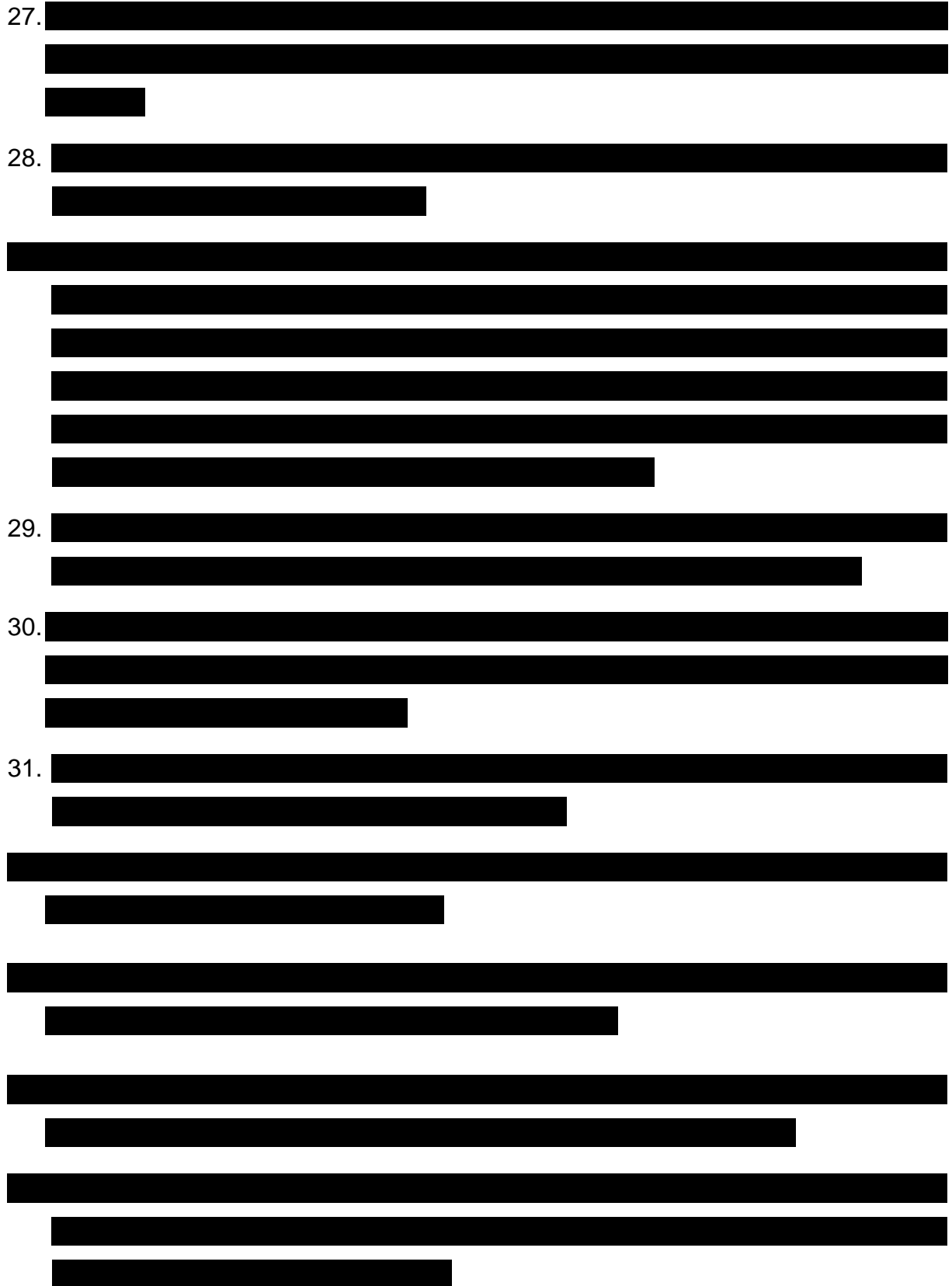












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