



**ESBRIET® (PIRFENIDON) W LECZENIU
ŁAGODNEJ DO UMIARKOWANEJ
POSTACI IDIOPATYCZNEGO WŁÓKNIENIA
PŁUC U OSÓB DOROSŁYCH**

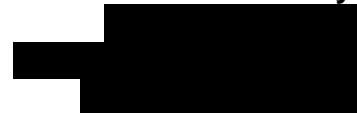
ANALIZA EKONOMICZNA

Wersja 1.1

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

[REDACTED]

[REDACTED]

[REDACTED]

Konflikt interesów:

Raport wykonano na zlecenie firmy InterMune International AG, która finansowała pracę.

Autorzy nie mieli innego rodzaju konfliktu interesów.

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Indeks skrótów

Skrót	Rozwinięcie
6MWT	ang. <i>6-min walk test</i> – test 6-cio minutowego marszu
AIAT	aminotransferaza alaninowa
AOTM	Agencja Oceny Technologii Medycznych w Polsce
AspAT	aminotransferaza asparaginianowa
b/d	brak danych
BSC	ang. <i>best supportive care</i> – optymalne leczenie wspomagające
CZN	cena zbytu netto
DL_{CO}	ang. <i>diffusing capacity for carbon monoxide</i> – zdolność dyfuzyjna dla tlenu węgla
FVC	ang. <i>forced vital capacity</i> – natężona pojemność życiowa
HRCT	ang. <i>high resolution computer tomography</i> - tomografia komputerowa wysokiej rozdzielczości
ICUR	ang. <i>incremental cost-utility ratio</i> - inkrementalny współczynnik kosztów-użyteczności
IPF	ang. <i>idiopathic pulmonary fibrosis</i> – idiopatyczne włóknienie płuc
kaps.	kapsułka
n/d	nie dotyczy
NICE	ang. <i>National Institute for Health and Clinical Excellence</i> – Narodowy Instytut Zdrowia i Doskonałości Klinicznej zajmujący się oceną technologii medycznych w Wielkiej Brytanii
NPC	naturalny przebieg choroby
PIR	pirfenidon
PL	program lekowy
PLC	placebo
PRISMA	ang. <i>Preferred Reporting Items of Systematic Reviews and Meta-Analyses</i> – preferowany sposób raportowania wyników przeglądów systematycznych i metaanaliz
RSS	ang. <i>risk sharing scheme</i> – umowa podziału ryzyka
QoL	ang. <i>quality of life</i> – jakość życia
SGRQ	ang. <i>St. George's Respiratory Questionnaire</i> – kwestionariusz używany do oceny jakości życia zależnej od stanu zdrowia, specyficzny dla chorych z obturacyjną chorobą płuc
TKWR	tomografia komputerowa wysokiej rozdzielczości
UCSD SOBQ	ang. <i>University of California, San Diego Shortness of Breath Questionnaire</i> – kwestionariusz oceniający nasilenie duszności opracowany na Uniwersytecie Kalifornijskim w San Diego

Streszczenie

CEL I ZAKRES ANALIZY

Celem analizy była ocena opłacalności stosowania w Polsce pirfenidonu (nazwa handlowa Esbriet®) w leczeniu dorosłych chorych z idiopatycznym włóknieniem płuc w postaci łagodnej do umiarkowanej. Doboru komparatorów dokonano na podstawie przeprowadzonej *Analizy klinicznej*.

METODYKA

[Redacted content]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Do oceny kosztów oraz efektów zdrowotnych przyjęto [REDACTED]

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[REDACTED]

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		[REDACTED]	[REDACTED]
T	[REDACTED]	[REDACTED] [REDACTED]	[REDACTED] [REDACTED]
	[REDACTED]	[REDACTED] [REDACTED]	[REDACTED] [REDACTED]

[REDACTED]

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[REDACTED]

WNIOSKI

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. Cel i zakres analizy ekonomicznej

Analiza została przygotowana w celu oceny opłacalności stosowania w Polsce pirfenidonu (nazwa handlowa Esbriet®) w leczeniu dorosłych chorych z idiopatycznym włóknieniem płuc w postaci łagodnej do umiarkowanej.

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2. Strategia analityczna

[REDACTED]

[REDACTED]

[REDACTED]

3. Perspektywa i horyzont czasowy

Zgodnie z *Rozporządzeniem Ministra Zdrowia z dnia 2 kwietnia 2012 r.* [18] analiza została wykonana zarówno z perspektywy podmiotu zobowiązanego do finansowania świadczeń ze środków publicznych (zwanej dalej perspektywą płatnika publicznego), jak i z perspektywy wspólnej podmiotu zobowiązanego do finansowania świadczeń ze środków publicznych i świadczeniobiorcy (zwaną dalej perspektywą wspólną).

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].

[REDACTED]

5. Dyskontowanie

W decyzji odnośnie 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.

[REDACTED]

6. Przegląd systematyczny badań do oceny jakości życia

Oprócz wyników zdrowotnych z badań klinicznych dotyczących skuteczności i bezpieczeństwa, w analizie ekonomicznej konieczne było określenie jakości życia chorych w analizowanym wskazaniu. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

6.1. Kryteria włączenia i wykluczenia badań do oceny jakości życia chorych

Poniżej przedstawiono kryteria ustanowione *a priori* w protokole do przeglądu systematycznego, na podstawie których decydowano o włączaniu badań do analizy.

Kryteria włączenia badań:

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

Kryteria wykluczenia badań:

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

6.2. Strategia wyszukiwania

W celu odnalezienia badań do oceny jakości życia chorych zastosowano strategie wyszukiwania.

Strategie wykorzystane do przeszukania bazy Embase i Medline ([REDACTED] [REDACTED]) oraz Cochrane Library zaprezentowano w rozdziale 21.1. Z kolei słowa kluczowe zastosowane do przeszukania bazy *Cost-Effectiveness Analysis Registry* (CEAR) przedstawiono w rozdziale 21.2.

[REDACTED]
[REDACTED]
[REDACTED]

6.3. Selekcja badań

Publikacje odnalezione w głównych bazach medycznych: Medline, Embase i Cochrane Library oraz w bazie CEAR zostały poddane selekcji na podstawie tytułów i streszczeń, a następnie pełnych tekstów. [REDACTED]

[REDACTED] Selekcję oparto na wcześniej zdefiniowanych kryteriach włączenia i wykluczenia.

Proces selekcji badań do oceny jakości życia zobrazowano na diagramie, przedstawionym w załączniku (Rozdział 21.3).

6.4. 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]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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

[REDACTED]

[REDACTED]

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7.2. Skuteczność kliniczna i profil bezpieczeństwa

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

8.1. Kryteria włączenia i wykluczenia innych analiz ekonomicznych

Poniżej przedstawiono kryteria ustanowione *a priori* w protokole do przeglądu systematycznego, na podstawie których decydowano o włączaniu badań do analizy.

Kryteria włączenia badań:

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

Kryteria wykluczenia badań:

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

8.2. Strategia wyszukiwania

W celu odnalezienia innych analiz ekonomicznych dotyczących omawianego problemu zdrowotnego przeszukano bazy informacji medycznej: Embase i Medline

([REDACTED]) oraz Cochrane Library. Zastosowano strategie wyszukiwania, które zaprezentowano w załączniku (Rozdział 21.1).

Dodatkowo w analizie przeszukano bazy:

- *Cost-Effectiveness Registry* (CEAR) [6], w której do odnalezienia analiz ekonomicznych zastosowano słowa kluczowe związane z problemem zdrowotnym oraz stosowaną interwencją,
- *National Institute for Health and Clinical Excellence* (NICE), w której do odnalezienia analiz ekonomicznych zastosowano pojęcie „pirfenidone”.

Strategie przeszukania bazy CEAR zaprezentowano w załączniku (Rozdział 21.2). W przypadku strony NICE użyto słowa kluczowego: *pirfenidone*.

8.3. Selekcja badań

Publikacje odnalezione w głównych bazach medycznych: Medline, Embase i Cochrane Library oraz bazach dodatkowych: CEAR oraz NICE zostały poddane selekcji na podstawie tytułów i streszczeń, a następnie pełnych tekstów [REDACTED]

[REDACTED] Selekcję oparto na wcześniej zdefiniowanych kryteriach włączenia i wykluczenia, opisanych w Rozdziale 8.2.

Proces selekcji innych analiz ekonomicznych zobrazowano na diagramie, przedstawionym w załączniku (Rozdział 21.3).

8.4. 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 bazy:

- *Cost-Effectiveness Analysis Registry*, w której odnaleziono [REDACTED]
[REDACTED]
[REDACTED]
- *National Institute for Health and Clinical Excellence*, w której odnaleziono [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

8.5. Metodyka włączonych publikacji prezentujących wyniki innych analiz ekonomicznych

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

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

[REDACTED]

9. Technika analityczna

[REDACTED]

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

10. 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.

W niniejszej analizie brano pod uwagę następujące koszty:

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

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

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[REDACTED]				

[REDACTED]

[REDACTED]

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11. Modelowanie

Ocenę opłacalności stosowania pirfenidonu we wskazanej populacji wykonano w porównaniu do naturalnego przebiegu choroby (nieleczenia). [REDACTED]

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12. Walidacja modelu

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13. Przedstawienie wyników

13.1. Analiza kosztów-konsekwencji

W ramach analizy ekonomicznej, do oceny opłacalności stosowania pirfenidonu w leczeniu łagodnej do umiarkowanej postaci idiopatycznego włóknienia płuc u osób dorosłych przeprowadzono analizę kosztów-konsekwencji. [REDACTED]

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14. Jednokierunkowa analiza wrażliwości

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14.1. Perspektywa płatnika publicznego

14.1.1. Wyniki jednokierunkowej analizy wrażliwości

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14.1. Perspektywa wspólna

14.1.3. Wyniki jednokierunkowej analizy wrażliwości - [REDACTED]

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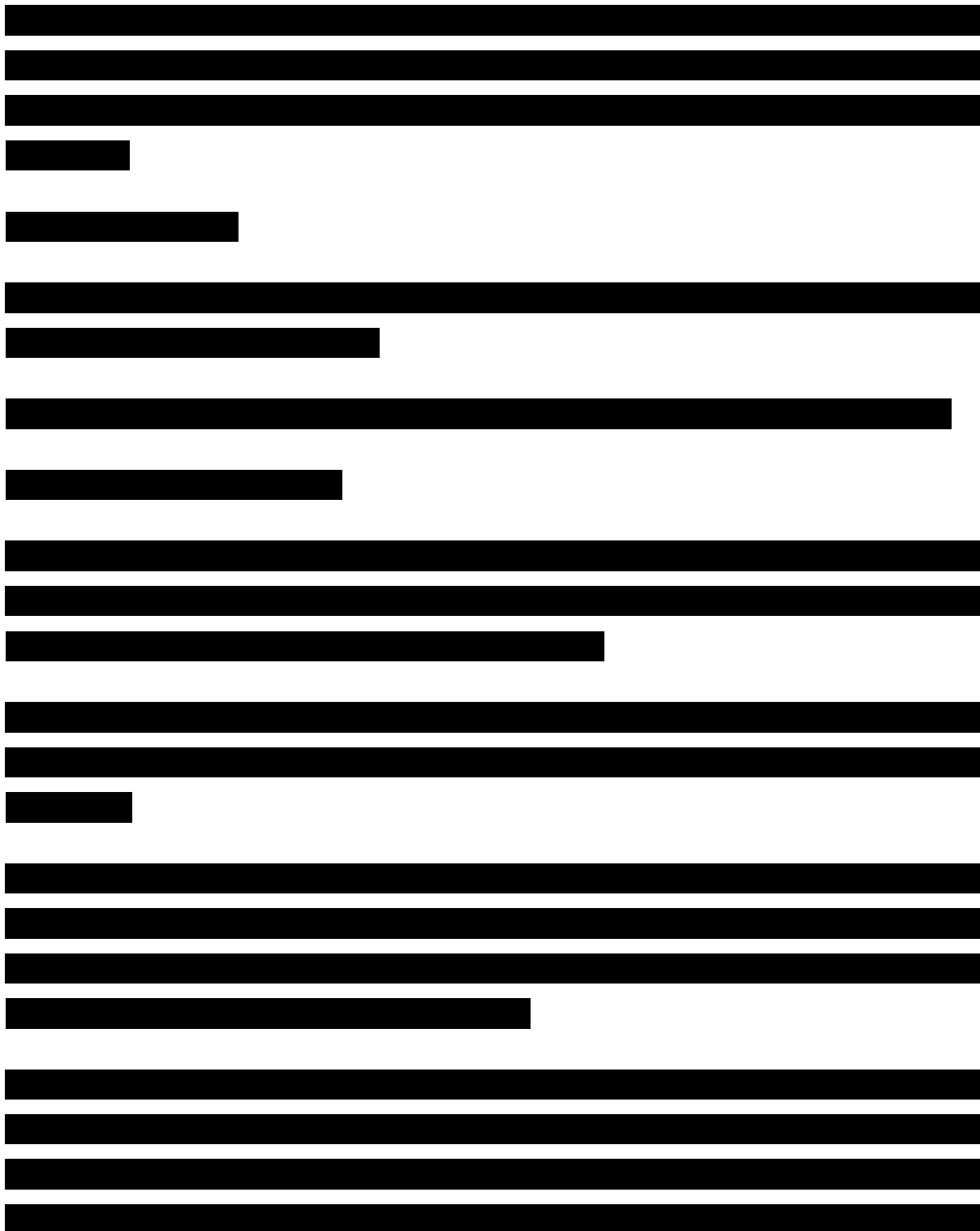
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14.2. Podsumowanie wyników jednokierunkowej analizy wrażliwości



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15. Wielokierunkowa analiza wrażliwości

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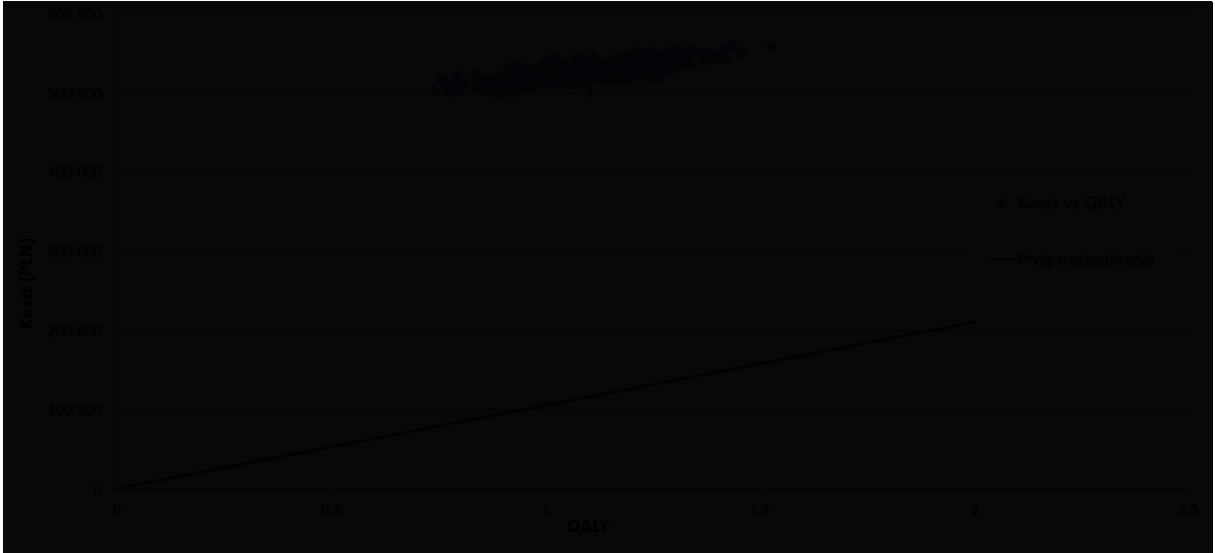
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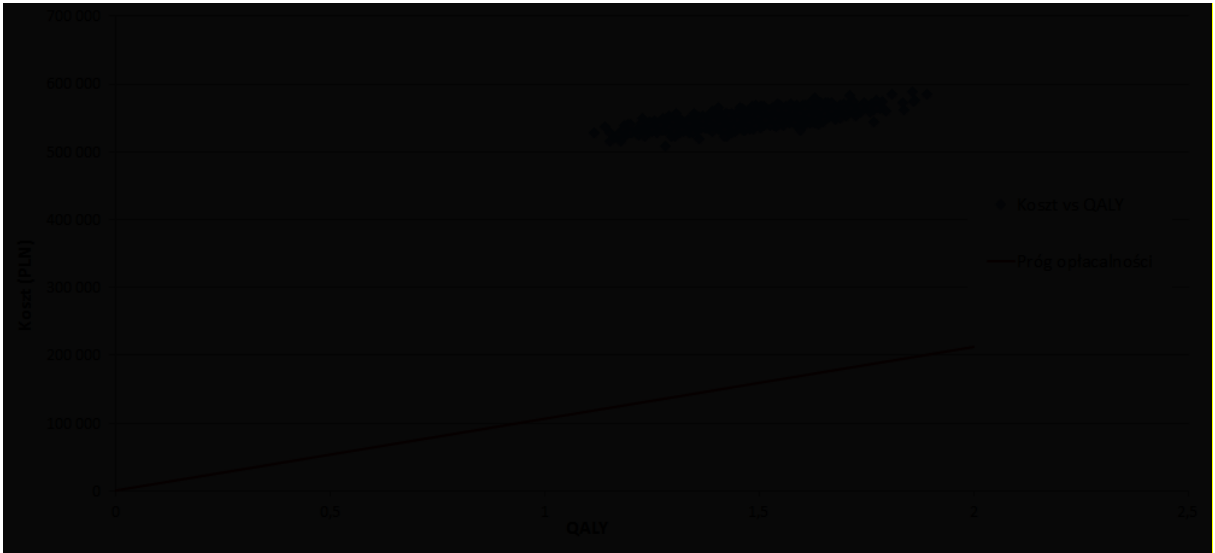
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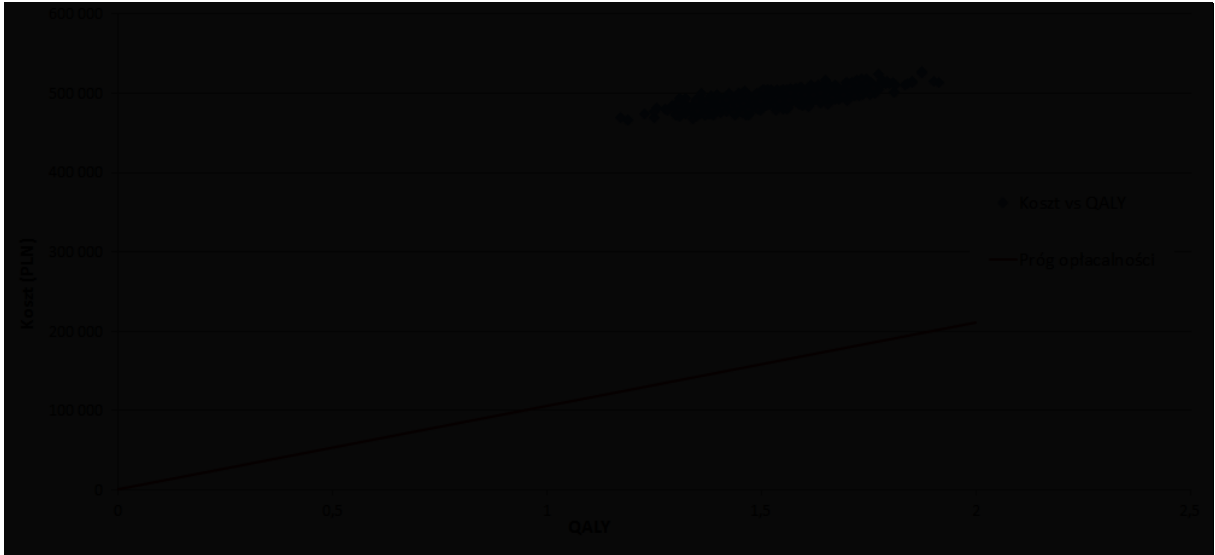
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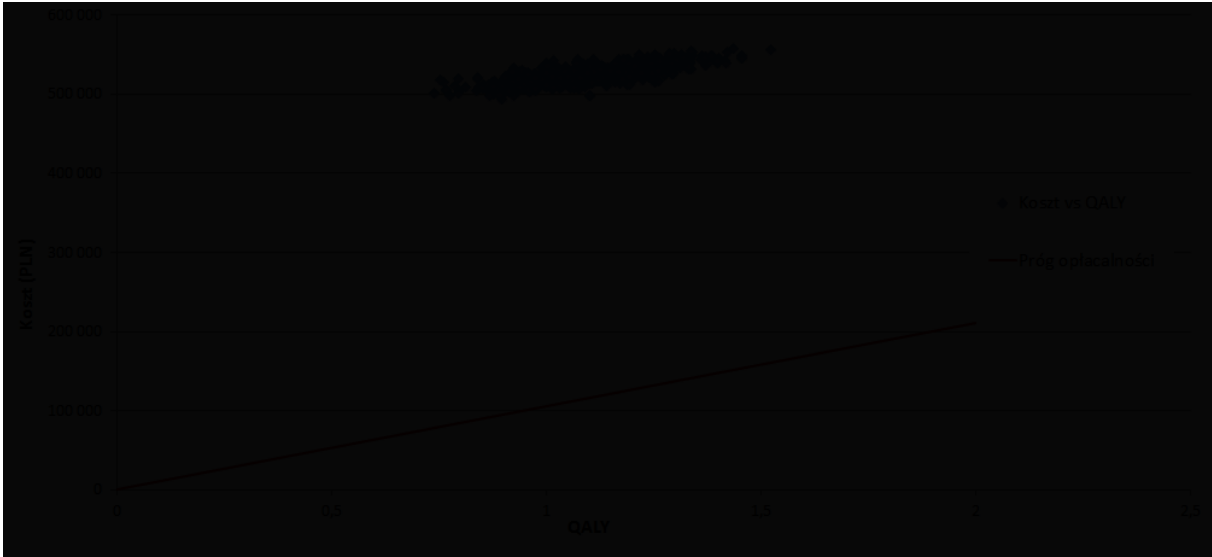
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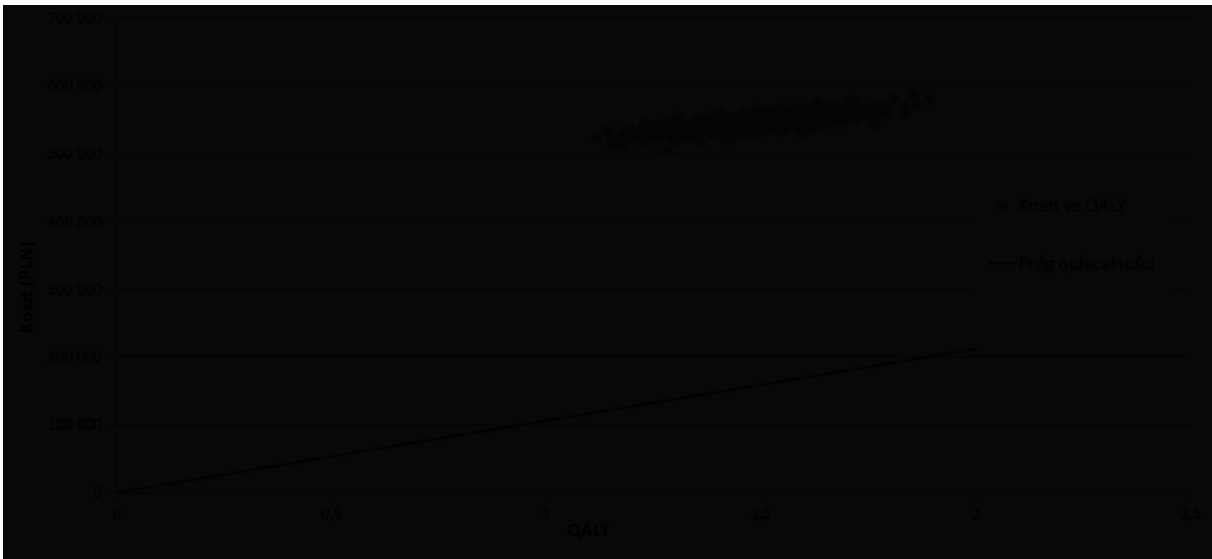
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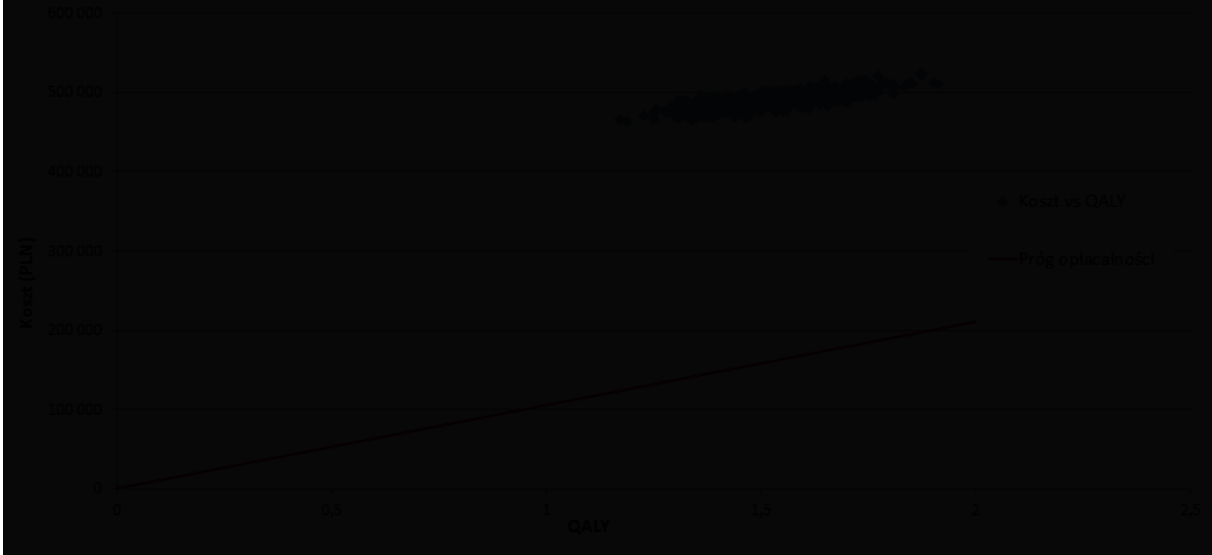
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16. Analiza progowa

Zgodnie z *Rozporządzeniem Ministra Zdrowia z 2 kwietnia 2012 r.* art. 5 ust. 2 pkt. 4 niniejsza analiza powinna zawierać cenę zbytu netto preparatów Esbriet®, przy której ICUR terapii pirfenidonem jest równy wysokości progu opłacalności, który obecnie wynosi 105 801 PLN/QALY (3 x PKB per capita). [REDACTED]

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17. Obszary rozbieżności między częścią kliniczną a kosztową

17.1. Badania wykorzystane do oceny skuteczności i opłacalności

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17.2. Sposób prezentacji efektu zdrowotnego

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17.3. Prezentacja zdarzeń w czasie

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17.4. Zakres danych wykorzystywanych do przedstawienia wyników

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18. Ograniczenia

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19. Podsumowanie i wnioski końcowe

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21. Załączniki

21.1. Strategie wyszukiwania zastosowane w bazach Embase, Medline i Cochrane Library do odnalezienia badań oceniających jakość życia chorych oraz innych analiz ekonomicznych wraz z liczbą publikacji odnalezionych dla poszczególnych zapytań

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21.2. Słowa kluczowe zastosowane w bazie dodatkowej wraz z liczbą publikacji odnalezionych dla poszczególnych zapytań

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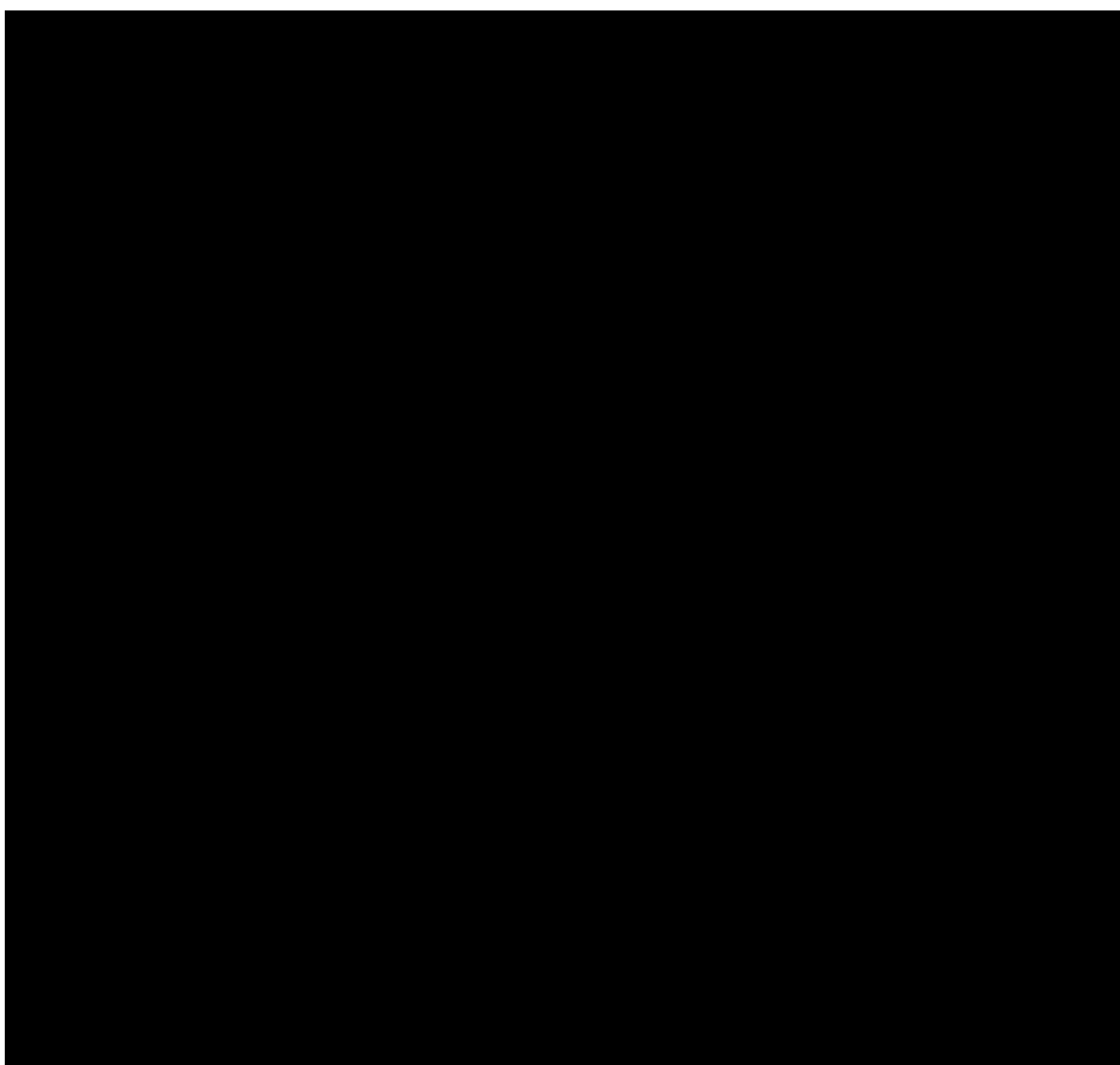
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21.3. Diagram PRISMA przedstawiający proces selekcji publikacji włączonych w ramach przeglądu systematycznego



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