



**TARGIN® (OKSYKODON+NALOKSON)
W LECZENIU DOROSŁYCH CHORYCH
Z SILNYM BÓLEM ORAZ W ZAPOBIEGANIU
ZAPARCIOM WYWOŁANYM PRZEZ OPIOIDY**

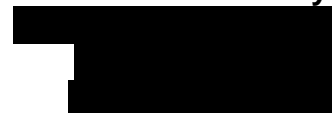
ANALIZA EKONOMICZNA

Wersja 1.1

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Warszawa, 3 grudnia 2013 r.

W dniu 2 grudnia 2013 r. analiza ekonomiczna została zaktualizowana w związku z uwagami zawartymi w Piśmie MZ-PLR-460-14222-22/JA/13 z dnia 13 listopada 2013 r. Pierwotnie analiza została zakończona 7 sierpnia 2013 r.

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

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Indeks skrótów

Skrót	Objaśnienie
AOTM	Agencja Oceny Technologii Medycznych
BFI	ang. <i>Bowel Function Index</i> – indeks czynności jelit
CCA	ang. <i>cost-consequences analysis</i> – analiza kosztów-konsekwencji
CRD	ang. <i>Centre for Reviews and Dissemination</i> – Centrum Przeglądów i Rozpowszechniania brytyjskiej służby zdrowia
CUA	ang. <i>cost-utility analysis</i> – analiza kosztów-użyteczności
EQ-5D	ang. <i>European Quality of Life-5 Dimensions</i> – europejski kwestionariusz do oceny jakości życia w 5 aspektach
ICUR	ang. <i>incremental cost-utility ratio</i> – inkrementalny współczynnik kosztów-użyteczności
MZ	Minister Zdrowia
NAL	nalokson
NFZ	Narodowy Fundusz Zdrowia
OKS	oksykodon
PKB	Produkt Krajowy Brutto
PAC-SYM	ang. <i>The Patient Assessment of Constipation Symptoms</i> – kwestionariusz oceny objawów zaparc przez chorego
PICOS	ang. <i>population, intervention, comparison, outcome, study design</i> – populacja, interwencja, komparatory, wyniki/punkty końcowe, metodyka
PIS	ang. <i>Pain Intensity Scale</i> – skala służąca do oceny nasilenia bólu
p.o.	łac. <i>per os</i> – podanie doustne
PPZ	postępowanie przeciwzaparciowe
PR	ang. <i>prolonged release</i> – postać leku o przedłużonym uwalnianiu
PRISMA	ang. <i>Preferred Reporting Items of Systematic reviews and Meta-Analyses</i> – preferowany sposób raportowania wyników przeglądów systematycznych

Skrót	Objaśnienie
	i metaanaliz
SD	ang. <i>standard deviation</i> – odchylenie standardowe
QALY	ang. <i>quality adjusted life years</i> – lata życia skorygowane o jakość
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 produktu leczniczego Targin® (oksykodon + nalokson) w leczeniu dorosłych chorych z silnym bólem, który może być właściwie leczony jedynie terapią opioidową. Dobór komparatorów oparto na przeprowadzonej *Analizie klinicznej*.

METODYKA

W celu oceny opłacalności stosowania produktu Targin® we wskazanej populacji chorych, zastosowano technikę analityczną kosztów-użyteczności, w której za jednostkę efektu zdrowotnego przyjęto lata życia skorygowane o jakość (QALY, ang. *quality-adjusted life years*). Do określenia współczynnika opłacalności stosowania oksykodonu w połączeniu z naloksonem względem oksykodonu (inkrementalny współczynnik kosztów-użyteczności, ICUR) posłużono się [REDACTED]

W analizie uwzględniono bezpośrednie koszty medyczne. Wyznaczono wartości dla następujących kategorii kosztowych, różniących oceniane technologie medyczne:

Do oceny kosztów oraz efektów zdrowotnych przyjęto [REDACTED] horyzont czasowy oraz perspektywę zarówno wspólną, jak i płatnika publicznego.

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WYNIKI

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[REDACTED]

Ponadto Targin® jest lekiem innowacyjnym, który działa nie tylko przeciwbólowo, ale także łagodzi zaparcia wywołane przez opioid. Należy podkreślić, że nalokson w ocenianym produkcie stosowany jest doustnie, dzięki czemu nie hamuje działania przeciwbólowego oksykodonu, w przeciwieństwie do naloksonu podawanego dożylnie. W przypadku zastosowania dożylnego lek osiąga odpowiednio wysokie stężenia we krwi i tkankach oraz dobrze przenika przez barierę krew–mózg (działa zarówno obwodowo, jak i ośrodkowo), przez co dochodzi do zniesienia wszystkich objawów wywołanych zastosowaniem opioidu, w tym działania przeciwbólowego.

1. Cel i zakres analizy ekonomicznej

Analiza została przygotowana w celu oceny opłacalności stosowania w Polsce produktu leczniczego Targin® (oksykodon + nalokson) w leczeniu dorosłych z silnym bólem, który może być właściwie leczony jedynie terapią opioidową.

Doboru komparatorów dokonano w oparciu o *Analizę kliniczną* [12]. W *Analizie klinicznej* jako komparator dla oksykodonu w połączeniu z naloksonem wskazano

[REDACTED]

Skuteczność oksykodonu w połączeniu z naloksonem względem oksykodonu wraz ze standardowym postępowaniem przeciwaparciowym w bólu nowotworowym została oceniona na podstawie badania *Ahmedzai 2012*.

Skuteczność oksykodonu w połączeniu z naloksonem względem oksykodonu wraz ze standardowym postępowaniem przeciwaparciowym w bólu głównie nienowotworowym została oceniona na podstawie badań *Löwenstein 2009*, *Meissner 2009* (publikacja *Nadstawek 2008*), *Vondrackova 2008* i *Simpson 2008*.

Na podstawie badań uwzględnionych w *Analizie klinicznej* [12] stwierdzono, iż dołączenie antagonisty receptorów opioidowych (naloksonu p.o.) do ich agonisty

(oksykodonu) nie wpływa na działanie przeciwbólowe oksykodonu, a ponadto powoduje osiągnięcie lepszej skuteczności przeciwwzparciowej przez analizowaną interwencję względem standardowego postępowania.

W związku z powyższym, w analizie ekonomicznej przeprowadzono porównanie opłacalności stosowania OKS+NAL względem OKS w leczeniu dorosłych z silnym bólem, który może być właściwie leczony jedynie terapią opioidową. Wyniki opłacalności prezentowane w oparciu o stworzony na potrzeby analizy model Markowa zaprezentowano jako wariant podstawowy analizy ekonomicznej.

2. Strategia analityczna

Analiza ekonomiczna opiera się na wykonanym od podstaw modelu (model wykonany *de novo*), w którym uwzględniono [REDACTED]

[REDACTED] Analizę oparto na badaniach odnalezionych w ramach *Analizy klinicznej* [12].

3. Perspektywa

Leczenie silnego bólu, który może być właściwie leczony jedynie terapią opioidową w Polsce współfinansowane jest z budżetu płatnika publicznego i pacjenta. Ze względu na sposób refundacji leków, pacjent partycypuje w kosztach związanych z leczeniem silnego bólu (który może być właściwie leczony jedynie terapią opioidową) w Polsce. Z tego względu analizę ekonomiczną wykonano zarówno z perspektywy wspólnej (płatnika publicznego i pacjenta), jak i 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].

[REDACTED]

5. 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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6.3.1. Ból nowotworowy

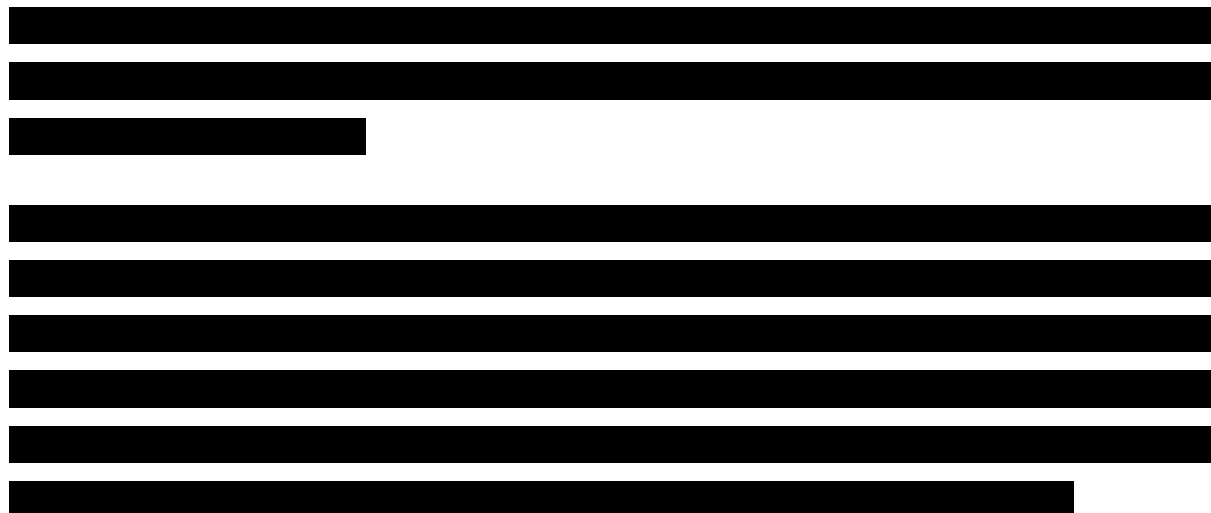
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6.3.2. Ból nienowotworowy

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7. Technika analityczna

Ponieważ zależna od zdrowia jakość życia jest w omawianym problemie zdrowotnym „jednym z istotnych wyników analizowanych technologii medycznych”, zdecydowano o przeprowadzeniu analizy ekonomicznej **techniką kosztów-użyteczności** (CUA, ang. *cost-utility analysis*) [1]. Jako efekt zdrowotny w analizie kosztów użyteczności przyjęto punkt końcowy wyrażany jako lata życia skorygowane o jakość (QALY, ang. *quality-adjusted life years*).

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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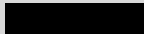

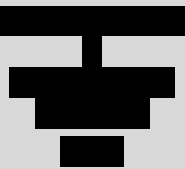
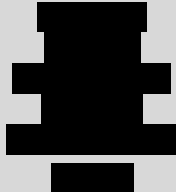
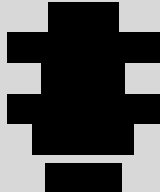
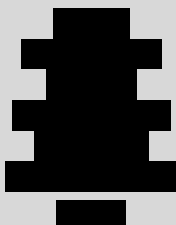

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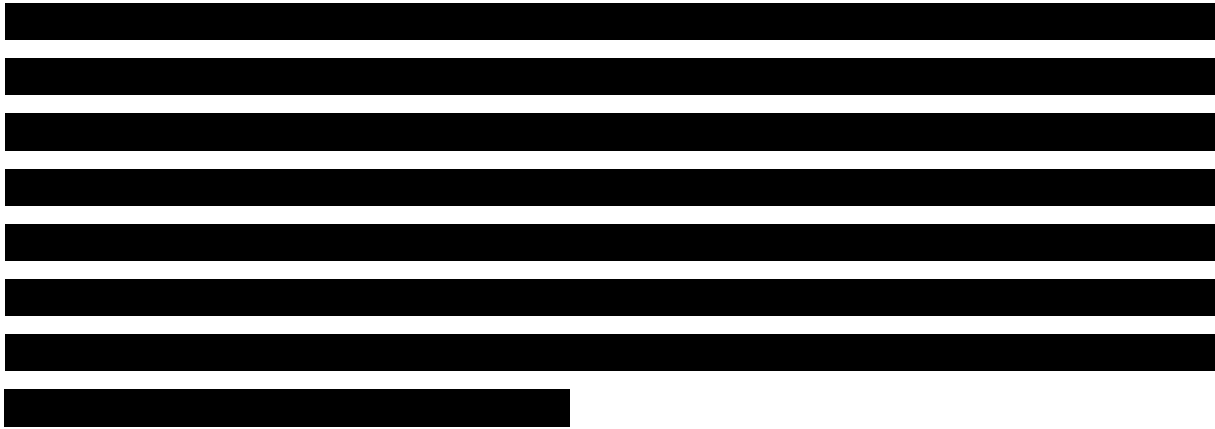
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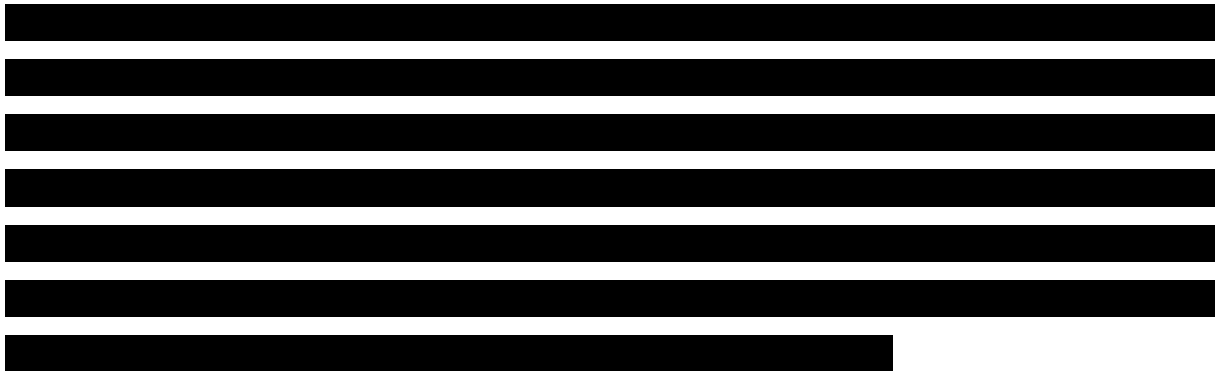
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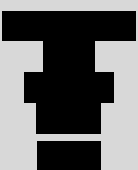
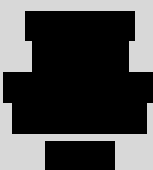

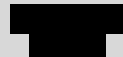
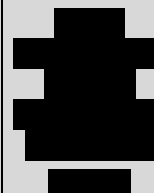
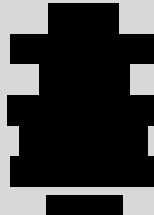
					
					









						
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10. Walidacja modelu

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11. Przedstawienie wyników

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11.1. Analiza kosztów-konsekwencji

Wyniki analizy kosztów-konsekwencji przedstawiają poniższe tabele.

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11.2. Analiza kosztów-użyteczności

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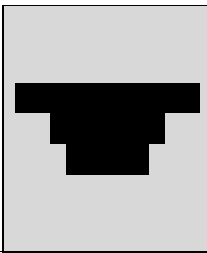
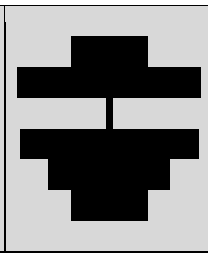
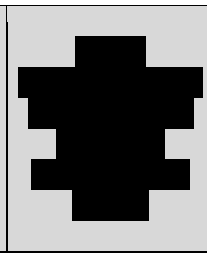
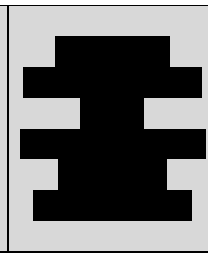
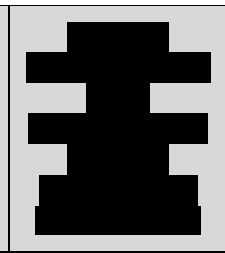
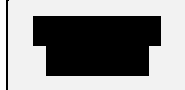





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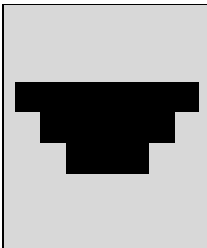
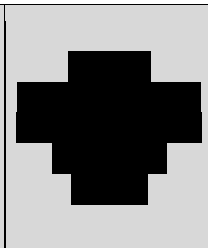
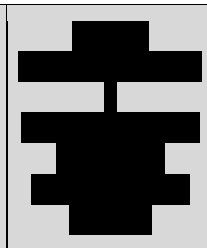
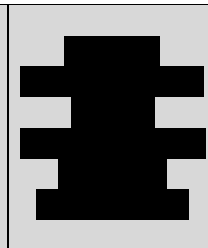
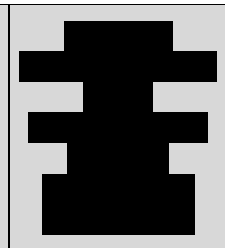


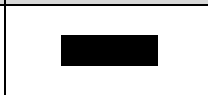
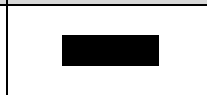
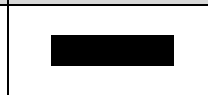
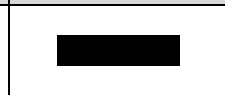
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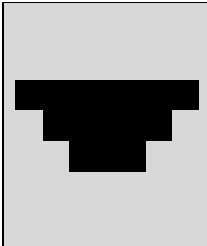
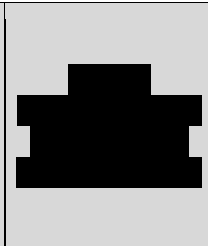
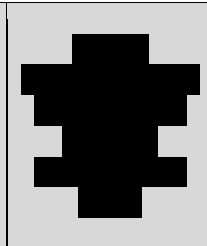
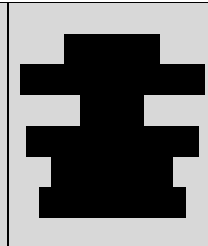
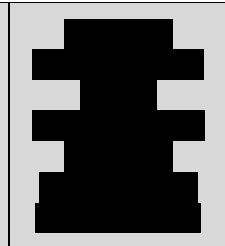


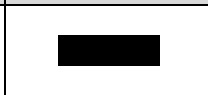
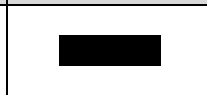
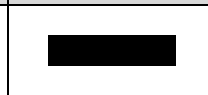
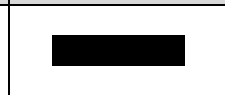
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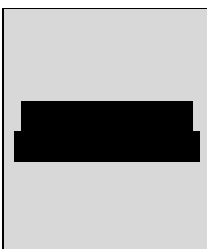
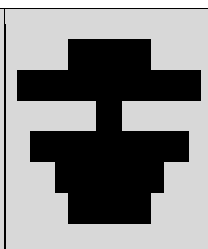
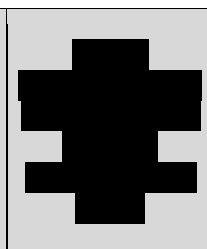
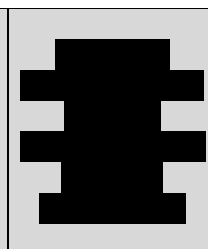
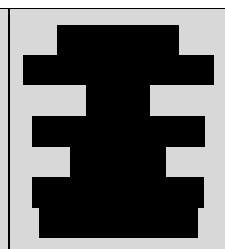


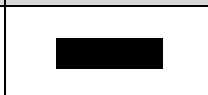
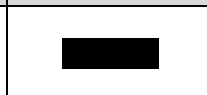
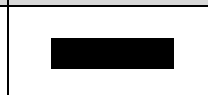
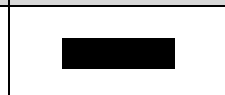
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²Wartości procentowe przedstawione w analizie wrażliwości odnieść należy do wartości współczynnika ICUR z analizy podstawowej.

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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* [29] (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* [34] (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* [32]). 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* [25] 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**.

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14. Wielokierunkowa analiza wrażliwości

W celu określenia niepewności wyników przeprowadzono wielokierunkową probabilistyczną analizę wrażliwości. Uwzględniono w niej wpływ zmiany wartości następujących parametrów na wartość ICUR:

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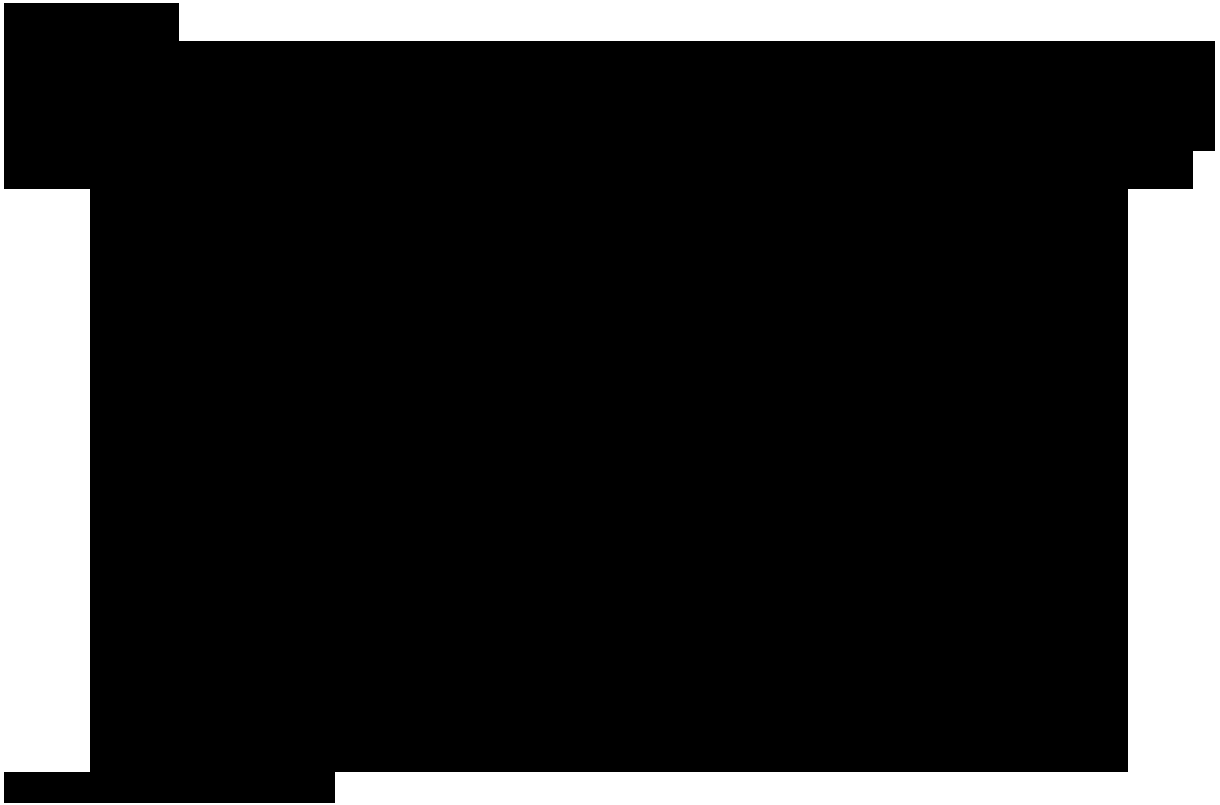
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15. Obszary rozbieżności między częścią kliniczną a kosztową

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16. Uzasadnienie utworzenia odrębnej grupy limitowej

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17. Ograniczenia i założenia

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19. Podsumowanie i wnioski końcowe

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20. Załączniki

20.1. Przegląd systematyczny badań do oceny jakości życia chorych w silnym bólu

Oprócz wyników zdrowotnych z badań klinicznych, w modelu konieczne było również określenie użyteczności poszczególnych stanów uwzględnionych w zbudowanym modelu. Z tego względu w niniejszej analizie wykonano przegląd systematyczny, mający na celu odnalezienie pożądaných danych.

20.1.1. 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:

- **populacja:** dorośli chorzy z silnym bólem (u których występują zaparcia), który może być właściwie leczony jedynie terapią opioidową;
- **metodyka:** badania pierwotne lub wtórne, w których dokonano oceny jakości życia chorych, z uwzględnieniem stanów przyjętych w modelu oraz punktów końcowych, określonych w badaniach, włączonych do *Analizy klinicznej*.

Kryteria wykluczenia badań:

- **populacja:** niezgodna z powyższymi kryteriami włączenia,
- **metodyka:** niezgodna z powyższymi kryteriami włączenia, przeglądy niesystematyczne, opisy przypadków tzw. *case-series*, opracowania poglądowe, publikacje w językach innych niż polski, angielski, niemiecki, francuski.

20.1.2. Strategia wyszukiwania

W celu odnalezienia badań do oceny jakości życia chorych zastosowano strategię wyszukiwania. Strategie zastosowane do przeszukania bazy Medline (poprzez wyszukiwarkę PubMed) 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 tej bazy zaprezentowano poniżej.

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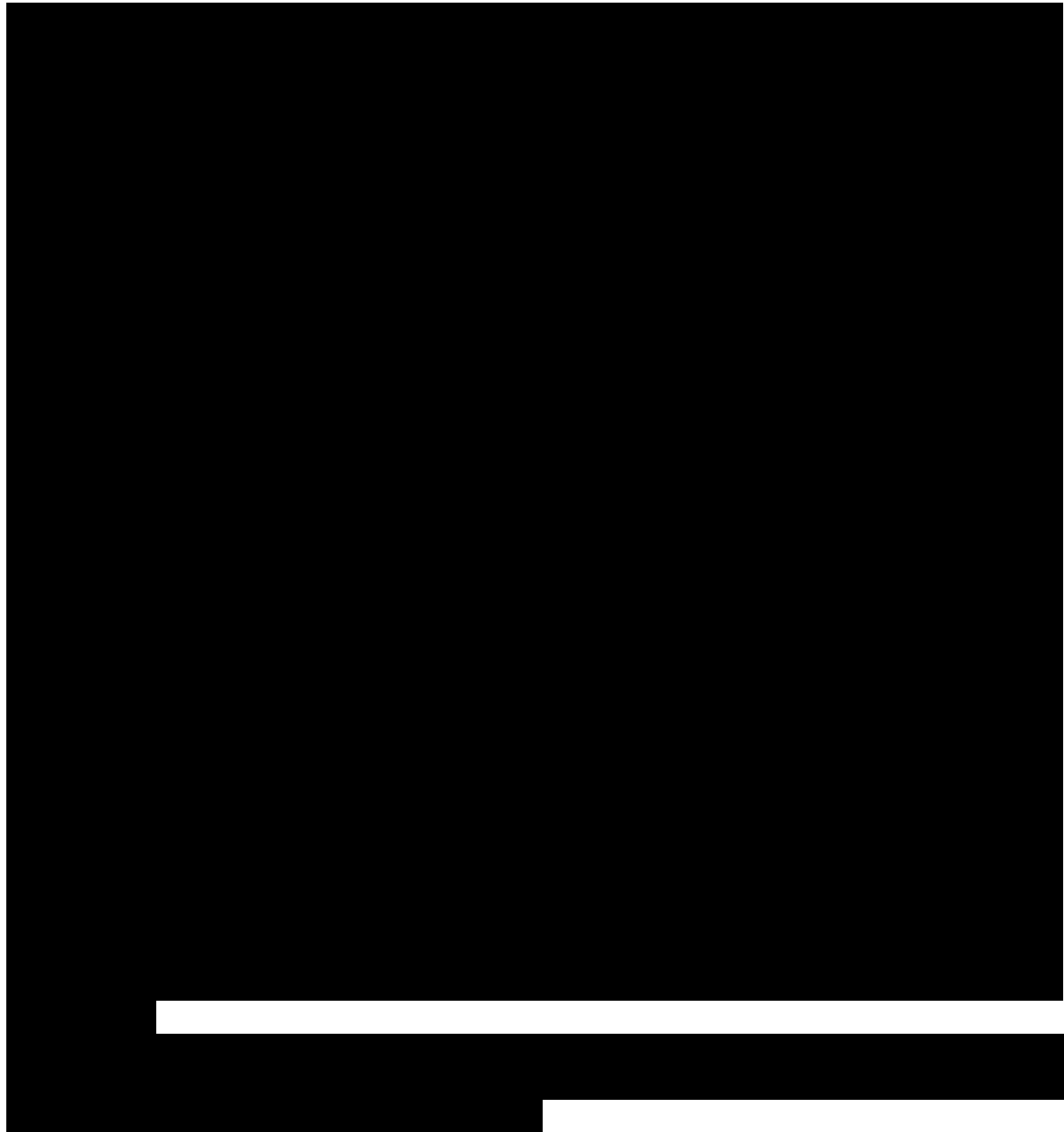
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Zakładanym wynikiem przeglądu było odnalezienie badań umożliwiających ocenę jakości życia chorych w analizowanym wskazaniu, z uwzględnieniem stanów przyjętych w modelu oraz punktów końcowych, określonych w badaniach, włączonych do *Analizy klinicznej*.

20.1.3. Selekcja badań

Odnalezione publikacje zostały poddane selekcji na podstawie tytułów i streszczeń, a następnie pełnych tekstów. Selekcji dokonało niezależnie dwóch analityków ██████████ ██████████ W przypadku braku zgodności decyzje podejmowane były z udziałem trzeciego analityka ██████████ na drodze konsensusu. Selekcję oparto na wcześniej zdefiniowanych kryteriach włączenia i wykluczenia, opisanych w rozdziale 20.1.1.

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



20.1.4. Publikacje do oceny jakości życia chorych odnalezione na podstawie przeglądu systematycznego i włączone do analizy

W wyniku przeszukiwania głównej bazy informacji medycznej (Medline przez wyszukiwarkę PubMed) odnaleziono [REDACTED] publikacji w formie tytułów i abstraktów.

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

20.2.1. Kryteria włączenia i wykluczenia innych analiz ekonomicznych

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

Kryteria włączenia badań:

- **populacja:** dorośli chorzy z silnym bólem (u których występują zaparcia), który może być właściwie leczony jedynie terapią opioidową;
- **interwencja:** oksykodon w połączeniu z naloksonem;
- **komparatory:** ██████████
- **metodyka:** analizy kosztów-efektywności, kosztów-użyteczności lub minimalizacji kosztów, wykonane w Polsce lub za granicą.

Kryteria wykluczenia badań:

- **populacja:** niezgodna z powyższymi kryteriami włączenia;
- **interwencja:** inna niż wyżej wymieniona;
- **komparatory:** inne niż wyżej wymienione;
- **metodyka:** niezgodna z powyższymi kryteriami włączenia, opracowania pogładowe, publikacje w językach innych niż polski, angielski, niemiecki, francuski.

20.2.2. Strategia wyszukiwania

W celu odnalezienia innych analiz ekonomicznych zastosowano strategie wyszukiwania. Strategie zastosowane do przeszukania bazy Medline (poprzez wyszukiwarkę PubMed) zaprezentowano poniżej. Strategie te zawierają terminy odnoszące się do wyżej zdefiniowanych kryteriów włączenia badań.

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20.2.3. Selekcja badań

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20.2.4. Inne analizy ekonomiczne odnalezione na podstawie przeglądu systematycznego i włączone do niniejszej analizy

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20.2.5. Metodyka włączonych publikacji prezentujących wyniki innych analiz ekonomicznych

[REDACTED]

Zgodnie z Wytycznymi AOTM, wyniki wskazanych powyżej analiz ekonomicznych przedstawiono w dyskusji (rozdział 18.).

20.3. Analiza wrażliwości dla [REDACTED]

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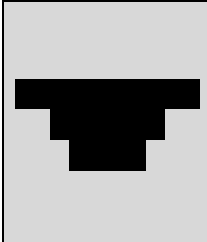
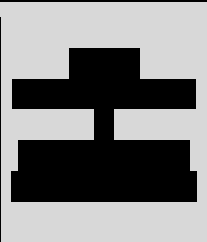
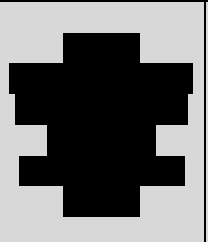
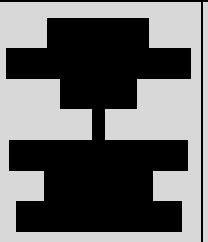
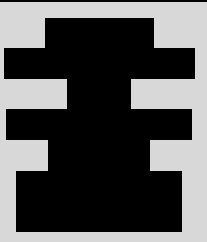






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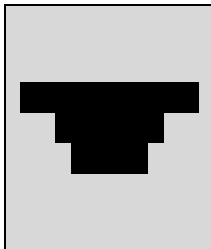
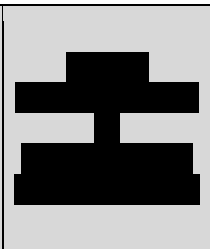
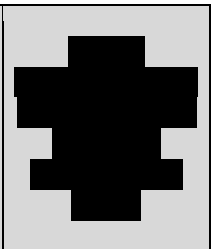
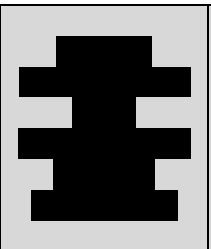
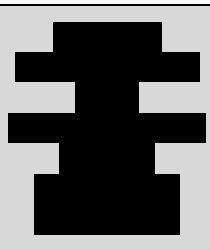
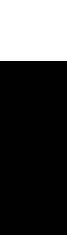





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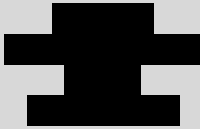




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20.5. Wyniki analizy dla poszczególnych prezentacji technologii wnioskowanej

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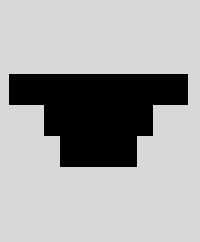
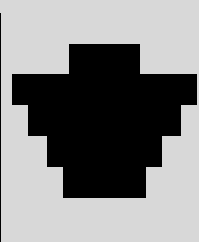
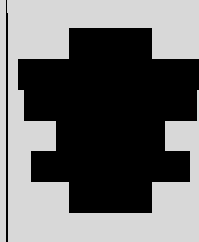
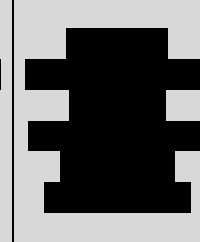
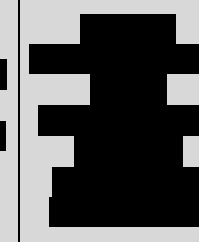






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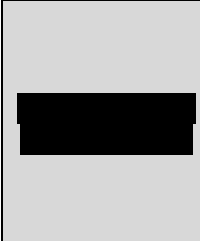
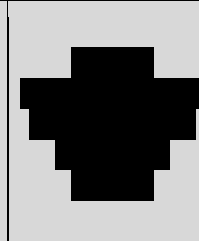
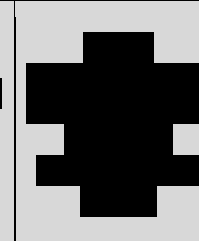
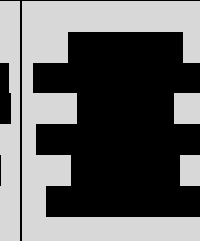
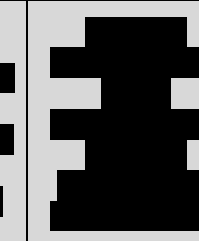






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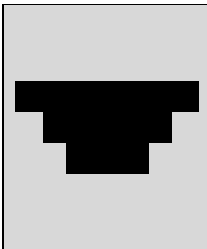
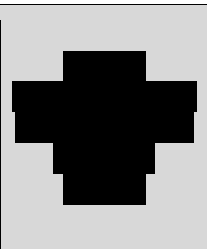
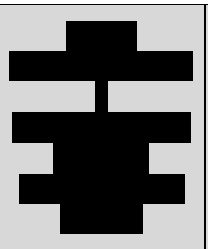
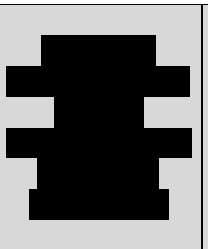
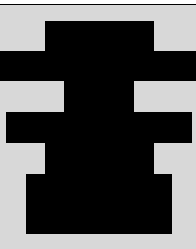

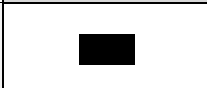
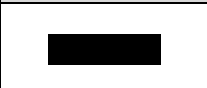
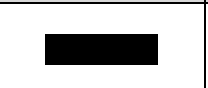
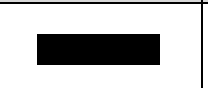
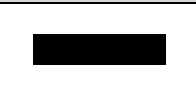
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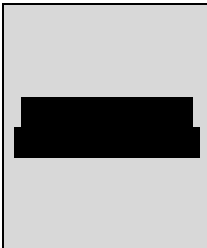
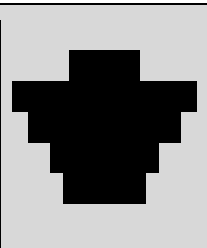
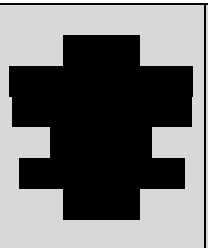
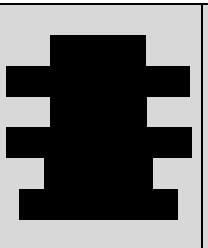
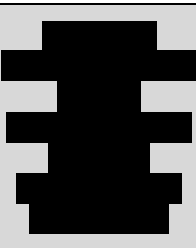


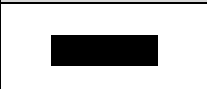
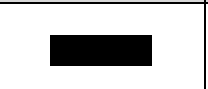
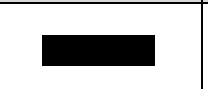
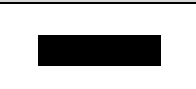
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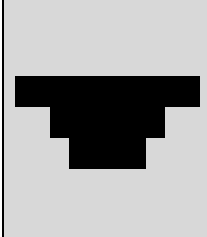
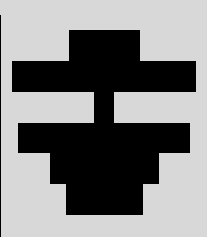
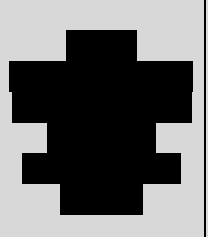
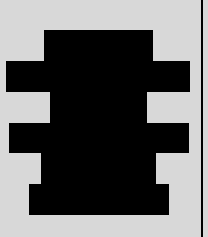
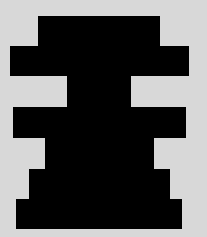


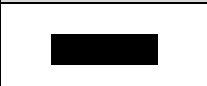
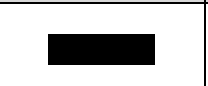
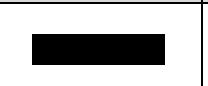
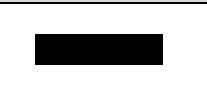
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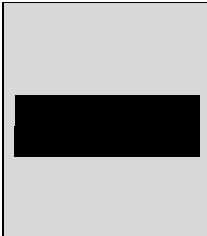
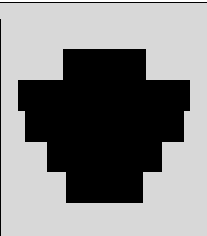
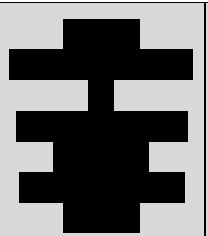
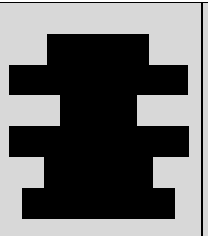
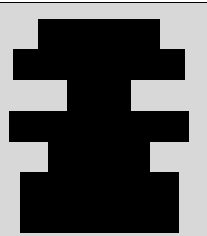


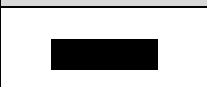
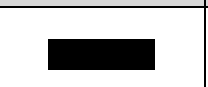
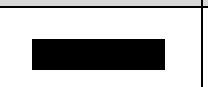
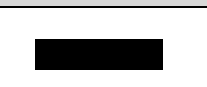
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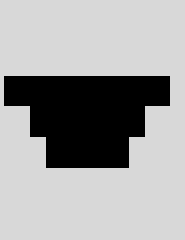
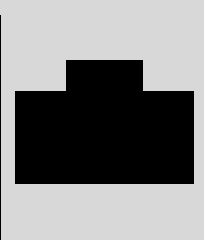
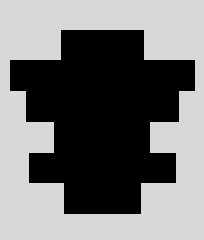
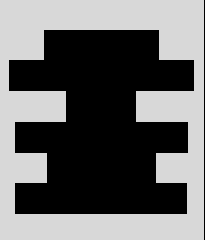
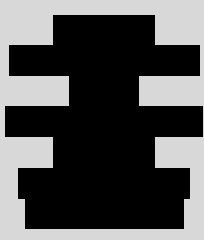






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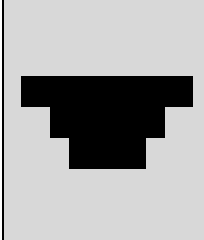
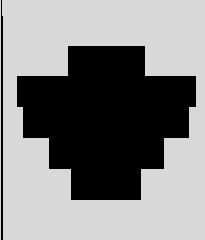
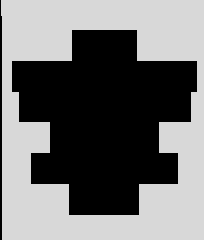
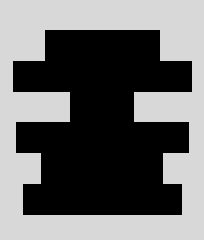
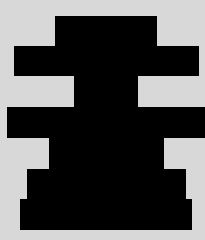






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Nazwa leku	Cena	Cena netto		Koszt		Cena		Cena	
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				Cena jednostki miary		Cena jednostki miary			
				z VAT	z VAT	z VAT	z VAT		
1	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
2	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
3	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
4	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
5	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
6	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
7	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
8	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
9	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
10	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
11	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
12	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
13	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
14	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
15	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
16	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
17	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
18	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
19	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	
20	Targin 10/0,1 mg/ml syrop	ml	1,00	1,00	1,20	1,20	1,00	1,00	

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