

Erbitux[®] (cetuksymab)



Analiza wpływu na system ochrony zdrowia

Wersja 1.1

Warszawa – Kraków 2014

Wykonawcy:

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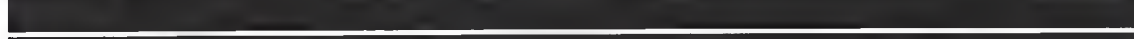


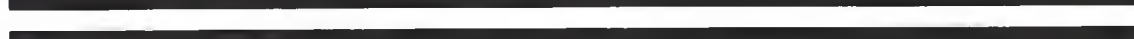
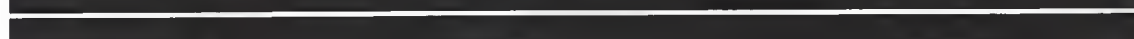

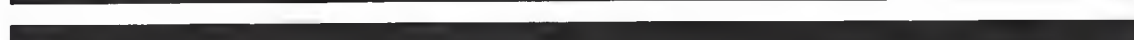




Konflikt interesów:

Raport został wykonany na zlecenie i sfinansowany przez firmę Merck Sp. z o.o.

Autorzy nie zgłosili konfliktu interesów.

Wersja 1.1 z dnia 09 maja 2014 r. – uzupełnienie wersji 1.0 z dnia 29 listopada 2013 r.

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Zgodność z Rozporządzeniem Ministra Zdrowia z 2 kwietnia 2012 r.

Uwaga AOTM	Komentarz
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Streszczenie

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Wnioski końcowe

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Wykaz skrótów

AEs	zdarzenia niepożądane (z ang. <i>adverse events</i>)
anty-EGFR	terapia molekularna ukierunkowana na EGFR (np. cetuksymab, panitumumab) (z ang. <i>epidermal growth factor receptor</i>)
AOTM	Agencja Oceny Technologii Medycznych
BIA	Analiza wpływu na budżet (z ang. <i>budget impact analysis</i>)
BSA	powierzchnia ciała (z ang. <i>body surface area</i>)
Cetux	Cetuksymab (z ang. <i>cetuximab</i>)
ChPL	charakterystyka produktu leczniczego
CRC	rak jelita grubego (z ang. <i>colorectal cancer</i>)
CTH	chemioterapia
DGL	Departament Gospodarki Lekami
ECOG	Eastern Cooperative Oncology Group
EGFR	receptor nabłonkowego czynnika wzrostu
GFR	Współczynnik przesączania kłębuszkowego (z ang. <i>glomerular filtration rate</i>)
i.v.	dożylne podanie leku (z łac. <i>in venam</i>)
JGP	Jednorodne Grupy Pacjentów
KRN	Krajowy Rejestr Nowotworów
LYG	zyskane lata życia (z ang. <i>life-years gained</i>)
mCRC	uogólniony rak jelita grubego (z ang. <i>metastatic colorectal cancer</i>)
MZ	Ministerstwo Zdrowia
NFZ	Narodowy Fundusz Zdrowia
NICE	National Institute for Health and Clinical Excellence
ORR	odsetek obiektywnych odpowiedzi (z ang. <i>overall response rate</i>)
OS	przeżycie całkowite (z ang. <i>overall survival</i>)
PCR	Reakcja łańcuchowa polimerazy (z ang. <i>Polymerase Chain Reaction</i>)
PFLYG	dotatkowe lata życia wolne od progresji choroby (z ang. <i>progression-free life years gained</i>)
PFS	przeżycie wolne od progresji choroby (z ang. <i>progression-free survival</i>)
PPL	projekt programu lekowego
PUO	Polska Unia Onkologii
RCT	badanie kliniczne z randomizacją i grupą kontrolną (z ang. <i>randomized controlled trial</i>)
RDI	względna intensywność dawki (z ang. <i>relative dose intensity</i>)
STA	Single Technology Appraisal
WHO	Światowa Organizacja Zdrowia (z ang. <i>World Health Organization</i>)

Analiza wpływu na system ochrony zdrowia

Rozdział

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1.1 Analiza wpływu na budżet płatnika

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1.1.3 Założenia dotyczące refundacji ze środków publicznych

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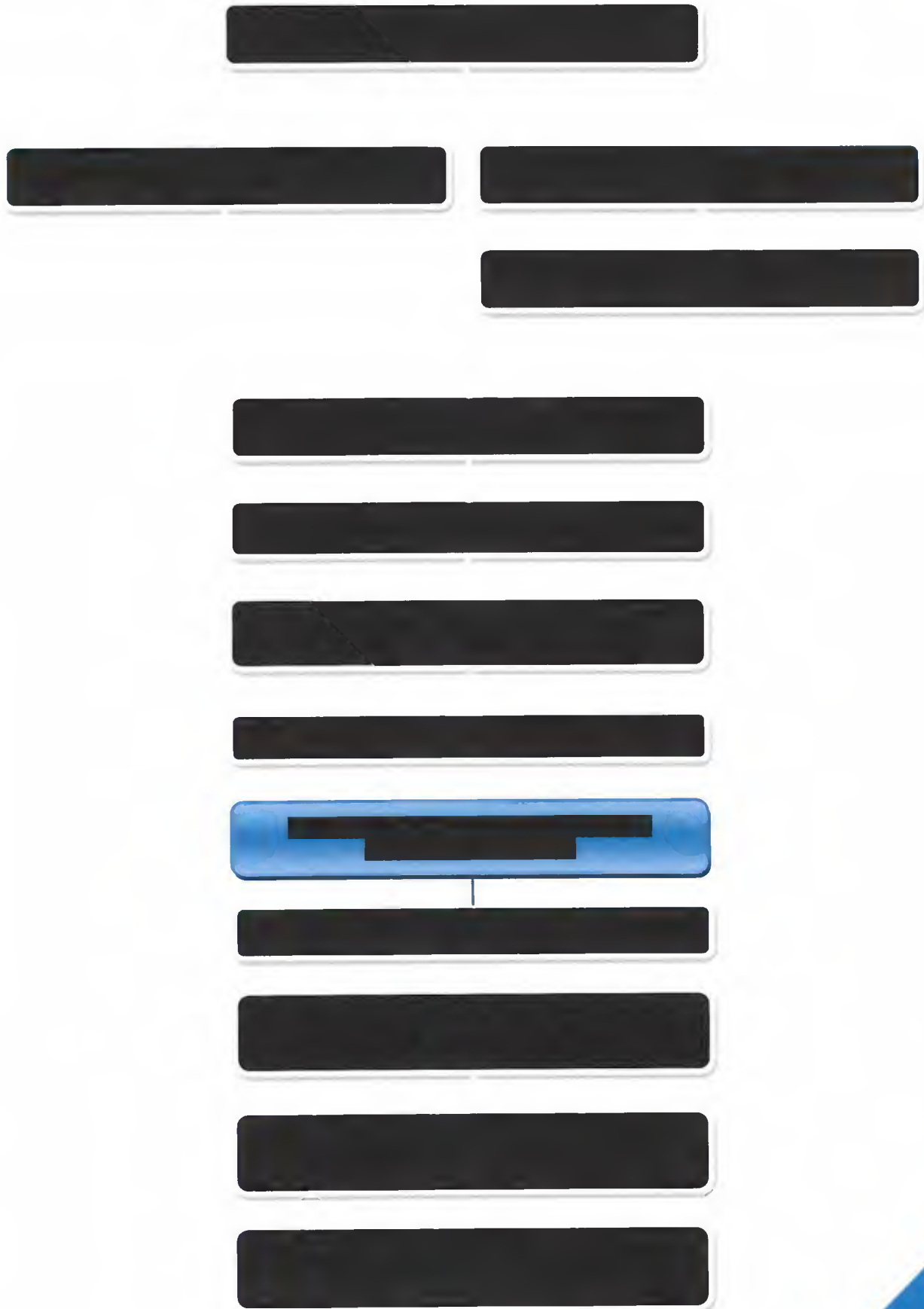
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1.1.8 Populacja docelowa

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1.1.8.1 Roczna zachorowalność na CRC

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1.1.8.2 Pierwotne uogólnienie - chorzy z rozpoznaniem w stadium przerzutowym (mCRC)

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1.1.8.14 Prognozowana liczebność populacji docelowej oraz liczebność chorych kwalifikowanych do programu leczenia za pomocą produktu leczniczego Erbitux® (cetuksymab)

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1.1.8.15 Prognozowane udziały i liczba leczonych w poszczególnych scenariuszach

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1.1.9 Oszacowanie rocznej liczebności populacji obejmującej wszystkich pacjentów, u których wnioskowana technologia może być zastosowana

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1.1.10 Oszacowanie rocznej liczebności populacji, w której wnioskowana technologia jest obecnie stosowana

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1.1.11 Analiza kosztów

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1.1.12 Wyniki analizy wpływu na budżet

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1.1.12.1 Oszacowanie aktualnych rocznych wydatków podmiotu zobowiązanego do finansowania świadczenia

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1.2 Wpływ na organizację udzielania świadczeń zdrowotnych

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1.3 Aspekty etyczne i społeczne

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1.4 Wnioski końcowe

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2. Piśmiennictwo

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- AOTM REK 59/2011** Rekomendacja nr 59/2011 Prezesa Agencji Oceny Technologii Medycznych z dnia 8 sierpnia 2011 r. w sprawie zmiany sposobu finansowania świadczenia opieki zdrowotnej „leczenie raka jelita grubego przy wykorzystaniu substancji czynnej cetuksymab” ze sposobu finansowania w ramach katalogu substancji czynnych w chemioterapii na finansowanie w ramach programu zdrowotnego
- AOTM-OT-0289** Erbitux® (cetuksymab) w leczeniu uogólnionego raka jelita grubego Ocena świadczenia opieki zdrowotnej. Raport Nr: AOTM-OT-0289. Warszawa, maj 2010.
- AOTM-OT-431-14** Leczenie raka jelita grubego przy wykorzystaniu substancji czynnej cetuksymab. Raport ws. oceny świadczenia opieki zdrowotnej. Raport Nr: AOTM-OT-431-14. Warszawa, sierpień 2011.
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- ChPL Erbitux** EMEA/H/C/000558 -II/0062 Erbitux. Charakterystyka Produktu Leczniczego – ostatnia aktualizacja dnia 27 stycznia 2014 r. Dostępne online pod adresem: <http://www.ema.europa.eu/>
Data ostatniego dostępu: 25 kwietnia 2014 r.
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**Komunikat DGL
23/10/2013**

Komunikat DGL z dnia 23 października 2013. Kwoty refundacji i liczba zrefundowanych opakowań jednostkowych leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz jednostkowych wyrobów medycznych narastająco od początku roku do lipca 2013 r. Załącznik: „Wartość wykonanych świadczeń dla substancji czynnych wykorzystywanych w programach terapeutycznych i chemioterapii (styczeń-lipiec 2013)”

http://www.nfz.gov.pl/new/art/5710/ref_w_chem_pl_sty_lip_2013.xls

**Komunikat DGL
23/10/2013**

Komunikat DGL z dnia 23 października 2013. Kwoty refundacji i liczba zrefundowanych opakowań jednostkowych leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz jednostkowych wyrobów medycznych narastająco od początku roku do lipca 2013 r. Załącznik: „Wartość wykonanych świadczeń dla substancji czynnych wykorzystywanych w programach terapeutycznych i chemioterapii (styczeń-lipiec 2013)”.

http://www.nfz.gov.pl/new/art/5710/ref_w_chem_pl_sty_lip_2013.xls

KRN 2013

Raporty na podstawie danych Centrum Onkologii. Dostępne on-line pod adresem:
<http://85.128.14.124/krn/>

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MZ 02/04/2012

Rozporządzenie Ministra Zdrowia z dnia 2 kwietnia 2012 r. w sprawie minimalnych wymagań, jakie muszą spełniać analizy zawarte w uzasadnieniu wniosku o objęcie refundacją i ustalenie urzędowej ceny zbytu, środka spożywczego specjalnego przeznaczenia żywieniowego, wyrobu medycznego, które nie mają odpowiednika refundowanego w danym wskazaniu.

MZ 08/12/2011

Rozporządzenie Ministra Zdrowia z dnia 8 grudnia 2011 r. zmieniające rozporządzenie w sprawie świadczeń gwarantowanych z zakresu programów zdrowotnych.

MZ 25/10/2013

Obwieszczenie Ministra Zdrowia z dnia 25 października 2013 r. w sprawie wykazu refundowanych leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych na dzień 1 listopada 2013 r.

MZ 23/04/2013

Obwieszczenie Ministra Zdrowia z dnia 23 kwietnia 2014 r. w sprawie wykazu refundowanych leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych na dzień 1 maja 2014 r.

NFZ 26/2012

Zarządzenie Nr 26/2012/DGL Prezesa Narodowego Funduszu Zdrowia z dnia 10 maja 2012 r. w sprawie określenia warunków zawierania i realizacji umów w rodzaju leczenie szpitalne w zakresie chemioterapia

- NFZ 27/2012** Zarządzenie Nr 27/2012/DGL Prezesa Narodowego Funduszu Zdrowia z dnia 10 maja 2012 r. w sprawie określenia warunków zawierania i realizacji umów w rodzaju leczenie szpitalne w zakresie programu zdrowotne (lekowe)
- NFZ 3/2013** Zarządzenie Nr 3/2013/DGL Prezesa Narodowego Funduszu Zdrowia z dnia 19 lutego 2013 r. zmieniające zarządzenie w sprawie określenia warunków zawierania i realizacji umów w rodzaju leczenie szpitalne w zakresie programu zdrowotne (lekowe) oraz zarządzenie w sprawie określenia warunków zawierania i realizacji umów w rodzaju: leczenie szpitalne
- NFZ 42/2013** Zarządzenie nr 42/2013/DGL Prezesa Narodowego Funduszu Zdrowia z dnia 9 sierpnia 2013 r. zmieniające zarządzenie w sprawie określenia warunków zawierania i realizacji umów w rodzaju leczenie szpitalne w zakresie programu zdrowotne (lekowe) oraz zarządzenie w sprawie określenia warunków zawierania i realizacji umów w rodzaju: leczenie szpitalne
- NFZ 45/2013** Zarządzenie Nr 45/2013/DSOZ Prezesa Narodowego Funduszu Zdrowia z dnia 30 sierpnia 2013 r. zmieniające zarządzenie w sprawie określenia warunków zawierania i realizacji umów w rodzaju: leczenie szpitalne
- NFZ 6/2013** Zarządzenie nr 6/2013/DGL Prezesa Narodowego Funduszu Zdrowia z dnia 22 lutego 2013 r. zmieniające zarządzenie w sprawie określenia warunków zawierania i realizacji umów w rodzaju leczenie szpitalne w zakresie chemioterapia
- NFZ 72/2011** Zarządzenie Nr 72/2011/DSOZ Prezesa Narodowego Funduszu Zdrowia z dnia 20 października 2011 r. w sprawie określenia warunków zawierania i realizacji umów w rodzaju: leczenie szpitalne
- NFZ 77/2012** Zarządzenie Nr 77/2012/DSOZ Prezesa Narodowego Funduszu Zdrowia z dnia 13 listopada 2012 r. zmieniające zarządzenie w sprawie określenia warunków zawierania i realizacji umów w rodzaju opieka paliatywna i hospicyjna

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Załączniki

Rozdział

III

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3.2 Refundowane preparaty substancji czynnych stosowanych w terapii mCRC

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3.3 Liczba i wartość zrefundowanych opakowań preparatów stosowanych w terapii mCRC

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3.6 Wkład autorów w opracowanie raportu

Autorzy	Udział w opracowaniu raportu
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

3.7 Spis tabel

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