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#### **4.7. Wpływ na organizację udzielania świadczeń zdrowotnych**

Wprowadzenie refundacji środka Neocate® Advance nie powinno spowodować konsekwencji dla wydatków publicznych w sektorach innych niż ochrona zdrowia. Ponadto stosowanie produktu Neocate® Advance nie wymaga dodatkowego przeszkolenia personelu, opracowania nowych wytycznych klinicznych, zmiany zasad diagnostycznych.

#### **4.8. Aspekty społeczne i etyczne**

Wprowadzenie refundacji środka Neocate® Advance nie powinno faworyzować jednych grup pacjentów/ubezpieczonych kosztem innych grup. Przy jednakowych potrzebach pacjentów/ubezpieczonych dostęp do nowego refundowanego środka spożywczego specjalnego

przeznaczenia medycznego powinien być niekwestionowany (decyzję o objęciu dietą elementarną podejmuje lekarz).

Pozytywna decyzja refundacyjna nie powinna stwarzać problemów społecznych, rodzinnych bądź dotyczących płci, powodować dylematów moralnych, grozić niezaakceptowaniem postępowania przez poszczególnych chorych, powodować lub zmieniać stygmatyzację, czy wywoływać lęk.

Decyzja refundacyjna dotycząca produktu Neocate® Advance nie stoi w sprzeczności z aktualnie obowiązującymi regulacjami prawnymi, nie stwarza konieczność dokonania zmian w prawie lub w przepisach oraz nie oddziałuje na prawa pacjenta lub prawa człowieka.

Stosowanie środka Neocate® Advance nie jest związane ze szczególnymi trudnościami dotyczącymi konieczności informowania pacjenta/ubezpieczonego lub uzyskiwania jego zgody na zastosowanie postępowania dietetycznego. Nie tworzy również trudności w zapewnieniu pacjentowi/ubezpieczonemu poufności leczenia, ani uwzględnianiu indywidualnych preferencji lub potrzeb czynnego udziału pacjenta/ubezpieczonego w podejmowaniu decyzji o wyborze metody leczenia.

Szacowana populacja docelowa dzieci powyżej 1 roku życia potencjalnie kwalifikujących się do stosowania diety elementarnej środkiem Neocate® Advance wynosi [REDACTED]. Z uwagi na istotny wpływ prowadzenia prawidłowej diety u dzieci (zwłaszcza w młodym wieku: 1-6 lat), wydaje się prawdopodobne uzyskanie dużej korzyści (prawidłowy rozwój dziecka) oraz pozytywnego wpływu na poziom satysfakcji (ustabilizowanie życia rodzinnego) w całej populacji dzieci powyżej 1 roku życia (stosujących refundowany środek Neocate® Advance) i ich rodzin.

Dzieci z ciężką postacią alergii na białka mleka krowiego oraz ze złożoną nietolerancją białek pokarmowych, u których występuje nietolerancja hydrolizatów o znacznym stopniu hydrolizy stanowią grupę osób o największych potrzebach zdrowotnych (brak prawidłowej diety w tak młodym wieku, może ograniczać prawidłowy rozwój dziecka). Dodatkowo do niedawna jedyną szansą prawidłowo prowadzonej diety był import docelowy odpowiedniej mieszanki (od 1 lipca 2012 roku wprowadzono refundację produktu Nutramigen® AA). Refundacja produktu Neocate® Advance w sposób zdecydowany poszerzy wachlarz refundowanych opcji dietetycznych, umożliwiając tym samym terapię, która umożliwia prawidłowy rozwój dzieci dotkniętych tymi schorzeniami.

Dieta elementarna przy użyciu produktu Neocate® Advance nie stanowi odpowiedzi na niezaspokojone dotychczas potrzeby grup społecznie upośledzonych.

Zgodnie z etykietą środka Neocate® Advance [7], produkt teoretycznie może być stosowany poza rozpatrywanym w niniejszej analizie wskazaniem (patrz opis populacji docelowej w rozdziale 4.2.1.1), jednakże z uwagi na aktualne polskie stanowisko w sprawie alergii [13] wydaje się wysoce prawdopodobne, iż zastosowanie produktu Neocate® Advance w szerszej populacji (dodatkowe wskazania zgodnie z etykietą [7]) będzie na znikomym poziomie.

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| [Redacted] | [Redacted] | [Redacted] | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] |
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| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
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[REDACTED]

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| [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] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |

[REDACTED]

[REDACTED]

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| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |

[REDACTED]