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4.7. Wpływ na organizację udzielania świadczeń zdrowotnych

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

4.8. Aspekty społeczne i etyczne

Wprowadzenie refundacji środka Neocate® LCP 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® LCP nie stoi w sprzeczności z aktualnie obowiązującymi regulacjami prawnymi, nie stwarza konieczności dokonania zmian w prawie lub w przepisach oraz nie oddziałuje na prawa pacjenta lub prawa człowieka.

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

Szacowana populacja docelowa niemowląt potencjalnie kwalifikujących się do stosowania diety elementarnej środkiem Neocate® LCP wynosi [REDACTED]. Z uwagi na istotny wpływ prowadzenia prawidłowej diety u niemowląt, wydaje się prawdopodobne uzyskanie dużej korzyści (prawidłowy rozwój dziecka) oraz pozytywnego wpływu na poziom satysfakcji (ustabilizowanie życia rodzinnego) w całej populacji niemowląt (stosujących refundowany środek Neocate® LCP) i ich rodzin.

Niemowlęta z ciężką postacią alergii na białka mleka krowiego oraz ze złożoną nietolerancją białek pokarmowych, u których występuje nietolerancja hydrolizatów o znacznym stopniu hydrolizy stanowiły grupę osób o największych potrzebach zdrowotnych (brak prawidłowej diety w tak młodym wieku, znacznie ogranicza 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® LCP w sposób zdecydowany poszerzy wachlarz refundowanych opcji dietetycznych,

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