Adalimumab (Hyrimoz®) w leczeniu umiarkowanej i ciężkiej postaci łuszczycy plackowatej

Odpowiedź na pismo OT.4230.5.2021.AZ.4 z dnia 12.03.2021 r.

Warszawa, marzec 2021

healthquest.pl

Autorzy

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HealthQuest

Odpowiedź na pismo AOTMiT o sygnaturze OT.4230.5.2021.AZ.4

W nawiązaniu do pisma AOTMiT o sygnaturze OT.4230.5.2021.AZ.4 poniżej przedstawiamy odpowiedzi i wyjaśnienia odnośnie do uwag w nim zawartych.

1) Informacje zawarte w analizach nie są aktualne na dzień złożenia wniosku (§2 Rozporządzenia):

W analizie problemu decyzyjnego (APD) nie uwzględniono aktualizacji wytycznych EADV/EDF/IPC 2017 (European Academy of Dermatology and Venereology/European Dermatology Forum/International Psoriasis Council) „European S3-Guideline on the systemic treatment of psoriasis vulgaris – Update Apremilast and Secukinumab – EDF in cooperation with EADV and IPC", opublikowanych 11 września 2017 roku, a więc przed datą złożenia wniosku.

Uprzejmie informujemy, że analizę problemu decyzyjnego uzupełniono o opis powyżej wymienionych wytycznych (tabela 10 APD). Zwracamy jednocześnie uwagę, że wskazany dokument dotyczy aktualizacji wytycznych w zakresie apremilastu i sekukinumabu i nie zawiera żadnych zmian dotyczących pozycjonowania adalimumabu w ścieżce terapeutycznej leczenia łuszczycy.

2) Przegląd systematyczny badań pierwotnych nie zawiera charakterystyki każdego z badań włączonych do przeglądu, w postaci tabelarycznej, z uwzględnieniem opisu metodyki badania (§ 4 ust. 3 pkt 5 lit. a, b, c, d, e, f, g i h Rozporządzenia):

Dla badań dotyczących efektywności praktycznej, tj. DermaReg, ESPRIT, PSOLAR, PsoRA, Leman 2020, Khobzey 2017, Chiricozzi 2017, Armesto 2015, Lopez-Ferrer 2013, nie przedstawiono pełnej charakterystyki metodyki badania w zakresie: rodzaju testowanej hipotezy, kryteriów włączenia/wyłączenia do badania, pełnej charakterystyki populacji, pełnej charakterystyki procedur, którym zostały poddane osoby badane (m.in. dawkowanie, schemat podawania), wykazu wszystkich ocenianych punktów końcowych, odsetka osób które przerwały leczenie przed zakończeniem badania, a także nie podano źródeł finansowania poszczególnych badań.

Uprzejmie informujemy, że analizę kliniczną uzupełniono o charakterystyki każdego z badań z zakresu efektywności praktycznej (rozdział 6 AK oraz aneks 6b).

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6) Przedłożone analizy nie zawierają wskazania innych źródeł informacji zawartych w analizach, w szczególności aktów prawnych oraz danych osobowych autorów niepublikowanych badań, analiz, ekspertyz i opinii (§8 pkt 1 oraz pkt 2 Rozporządzenia):

W przedłożonych analizach występują odwołania do źródeł, których nie można zidentyfikować oraz zweryfikować, tj. Kieszkowska Rutkowska Kolasiński 2020 - Kieszkowska Rutkowska Kolasiński. Dopuszczalność objęcia refundacją apteczną leku Hyrimoz refundowanego obecnie w Programach lekowych. Opinia prawna. Grudzień 2020.

Zwracamy uwagę, że analiza Kieszkowska Rutkowska Kolasiński 2020 - Kieszkowska Rutkowska Kolasiński została dołączona jako załącznik do wniosku refundacyjnego.

1 Analiza ekonomiczna

1.1 Koszty leczenia pacjentów po przerwaniu terapii adalimumabem

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2.1 Wyniki

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2 Analiza wpływu na budżet

3.1 Wyniki

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