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Odpowiedź na pismo
nr OT.423.1.7.2023.7.MRd

Warszawa, 2023

Autorzy

[redacted]

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Uwaga 1.

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Odpowiedź:

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Uwaga 2.

[redacted] Należy przedstawić porównanie z wszystkimi komparatorami refundowanymi we wnioskowanej populacji (§ 3-6 Rozporządzenia w całości)."

Odpowiedź:

Tralokinumab, podobnie jak dupilumab, stanowi lek biologiczny – przeciwciało monoklonalne wiążące IL-13. Z racji tego, że tralokinumab i dupilumab należą do tej samej grupy leków tj. leki biologiczne oraz ich wskazania refundacyjne pokrywają się w znacznym stopniu tj. dotyczą ciężkiej postaci AZS ([redacted]) zasadnym jest przyjęcie dupilumabu jako komparatora dla omawianej interwencji. Upadacytynib należy do innej grupy leków niż tralokinumab i dupilumab. Upadacytynib nie jest lekiem biologicznym, a selektywnym inhibitorem kinazy Janus (JAK1), który należy do selektywnych leków immunosupresyjnych. Ze względu na odmienną grupę leków w odniesieniu do tralokinumabu upadacytynib nie został wybrany jako komparator dla ocenianej interwencji. W związku z powyższym przyjęto, iż komparator dla tralokinumabu w ciężkiej postaci AZS stanowić będzie dupilumab - lek z tej samej grupy leków tj. leków biologicznych. Potencjalna wymiana terapii wśród pacjentów z AZS będzie zatem odbywała się w ramach grupy leków biologicznych.

Uwaga 3.

„W ramach analiz ekonomicznej oraz wpływu na budżet, wnioskodawca porównuje się z kosztami technologii porównywanych zaczerpniętymi z obwieszczeń MZ, jednak realne ceny komparatorów są niższe. Należy wskazać, że w chwili składania wniosku dostępne były komunikaty DGL na podstawie których możliwe było oszacowanie ceny realnej (§ 2 Rozporządzenia). Mając na uwadze możliwą istotną zmianę wyników analiz Agencja informuje, że na podstawie sprawozdanej i rozliczonej wartości świadczeń

- cena DUPI w 2022 r. wyniosła 5,9472 zł/mg (1 784,16 zł za amp.-strzyk.),
- cena UPA w 2022 r. wyniosła 4,5832 zł/mg,
- średnie roczne koszty BSC utrzymują się na poziomie 130 zł."

Odpowiedź:

Obliczenia przeprowadzone na potrzeby zarówno analizy ekonomicznej, jak i analizy wpływu na budżet, zostały zaktualizowane o wskazane powyżej ceny efektywne komparatorów. Do pisma dołączono odpowiednie pliki xls zawierające zaktualizowane wyliczenia.

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W poniższych tabelach (Tab. 7, [redacted]) zestawiono wyniki porównania tralokinumabu z dupilumabem, w którym przyjęto realną cenę DUPI na podstawie oszacowań Agencji (tj. 1 784,16 zł za amp.-strzyk.).

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Uwaga 4.

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Odpowiedź:

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Uwaga 5.

„W przypadku przedstawienia porównań z kolejnymi komparatorami oraz niewykazania wyższości nad refundowanymi komparatorami uprzejmie proszę o przedstawienie rankingu CUR z uwzględnieniem realnych cen, a następnie urzędowych cen zbytu, przy których koszt stosowania technologii wnioskowanej jest nie wyższy niż koszt stosowania komparatora o najniższym CUR. Rozporządzenie w aktualnym brzemieniu nie zezwala na zrównanie CUR w przypadku zachodzenia okoliczności opisanych w art. 13 ust. 3 Ustawy o Refundacji. [redacted] Uprzejmie proszę o przedstawienie cen wynikających z art. 13 ust. 3 UoR jako urzędowych cen zbytu, nie jako cen zbytu netto (§ 5. ust.6 pkt 3 Rozporządzenia)."

Odpowiedź:

Z uwagi na fakt, że w analizie minimalizacji kosztów nie przedstawiono innych komparatorów niż dupilumab, nie prezentowano rankingu CUR. W raporcie faktycznie przedstawiono progową cenę zbytu netto. Poniżej przedstawiono korektę obliczonej ceny progowej.

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Uwaga 6.

„Wnioskodawca nie przedstawił również właściwej do oceny analizy wpływu na budżet. [redacted]

Odpowiedź:

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Uwaga 7

„Wnioskodawca w analizach przedstawił wyniki badania ECZTRA-6. Analitycy Agencji nie odnaleźli publikacji dla ww. badania. Jednocześnie w analizach wnioskodawca nie przedstawia danych bibliograficznych umożliwiających identyfikację i weryfikację zamieszczonych informacji („data on file"). Proszę o przedstawienie pakietu danych (najlepiej z poziomu pacjenta) pozwalających na określenie charakterystyki populacji pacjentów wraz z wynikami skuteczności klinicznej tralokinumabu (§ 8 Rozporządzenia)."

Odpowiedź:

Publikację do badania ECZTRA-6, w której przedstawiono między innymi charakterystykę populacji pacjentów wraz z wynikami skuteczności klinicznej tralokinumabu, dołączono do niniejszego pisma.