Adalimumab

Statut de médicament essentiel ✓

EMLc | Codes ATC: L04AB04

Indication	Psoriasis of unspecified type Code ICD11: EA90.Z
INN	Adalimumab
Type de médicament	Biological agent
Type de liste	Liste complémentaire (EML) (EMLc)
Additional notes	*including quality-assured biosimilars.
Formulations	Parenteral > General injections > SC: 10 mg per 0.2 mL mL in pre-filled syringe or pre-filled pen. (EMLc) ; 20 mg per 0.2 mL mL in pre-filled syringe or pre-filled pen. (EMLc) ; 20 mg per 0.4 mL mL in pre-filled syringe or pre-filled pen. (EMLc) ; 40 mg per 0.4 mL mL in pre-filled syringe or pre-filled pen. ; 40 mg per 0.8 mL mL in pre-filled syringe or pre-filled pen. ; 80 mg per 0.8 mL mL in pre-filled syringe or pre-filled pen.
Historique des statuts LME	Ajouté pour la première fois en 2025 (TRS 1064)
Sexe	Tous
Âge	Aussi recommandé pour les enfants
Équivalence thérapeutique	certolizumab pegol (Codes ATC: L04AB05) etanercept (Codes ATC: L04AB01) infliximab (Codes ATC: L04AB02)
Renseignements sur le brevet	Patents have expired in most jurisdictions Lire la suite sur les brevets.
Wikipédia	Adalimumab
DrugBank	Adalimumab

Recommandation du comité d'experts

The Expert Committee considered that the inclusion of effective and safe biological medicines for psoriasis on the Model Lists would address an important public health need and support advocacy efforts to reduce the global burden of psoriasis, especially in low- and middle-income countries. The Committee acknowledged that a large number of biological disease-modifying medicines for psoriasis are available, and that there was a need to prioritize the most effective, tolerable and affordable options. The Committee noted that high-quality evidence supports the superior efficacy of adalimumab and other tumour necrosis factor (TNF)-alpha inhibitors over placebo in achieving Psoriasis Area and Severity Index responses in patients with moderate-to-severe psoriasis. The Committee also noted that adalimumab and alternative TNF-alpha inhibitors were superior to the non-biological treatments (e.g. methotrexate) typically used as first-line treatment currently included on the Model Lists. The Committee considered the safety profile of adalimumab to be well established, based on extensive clinical trial and real-world data across multiple indications. TNF-alpha inhibitors, including adalimumab, are associated with risks of serious infections and reactivation of latent tuberculosis or hepatitis B. The Committee recalled that adalimumab and other TNF-alfa inhibitors were already included on the Model Lists for other indications and are considered to be therapeutic alternatives to each other in most clinical scenarios. The Committee considered that including multiple within-class alternatives on the Model Lists could support greater competition to lower prices. The Committee also noted the wide availability of biosimilars of these medicines, which is also an important factor in achieving lower prices. Based on these considerations, the Expert Committee recommended the inclusion of adalimumab on the EML and EMLc for the treatment of adults and children with moderate-to-severe psoriasis. Listing is recommended for adalimumab with a square box, with certolizumab pegol, etanercept and infliximab (including quality-assured biosimilars) as therapeutic alternatives.

Contexte

Adalimumab (and alternative TNF-alpha inhibitors) have not previously been evaluated for inclusion on the Model Lists for use in the treatment of moderate-to-severe psoriasis. In 2019, adalimumab (as the representative TNF-alpha inhibitor) was added to the complementary list of the EML and EMLc for second-line treatment of severe chronic inflammatory autoimmune disorders (ankylosing spondylitis, Crohn disease , juvenile idiopathic arthritis and rheumatoid arthritis) on the basis of a favourable benefit-to-harm profile (1). In 2023, the Expert Committee recommended the addition of oral methotrexate on the complementary list of the EML and EMLc for second-line treatment of patients with psoriasis, given evidence of the favourable balance of desirable to undesirable effects (2). Before 2023, only topical therapies (coal tar, corticosteroids, salicylic acid and vitamin D analogues) were included on the Model Lists for treatment of psoriasis.

Pertinence pour la santé publique

The public health relevance of effective treatments for psoriasis has been accepted previously by the Expert Committee. Data for 2021 from the Global Burden of Disease study report a global prevalence of psoriasis of almost 53 million people and an annual global incidence of nearly 6 million. Psoriasis was responsible for 0.13% of global disability-adjusted life years in 2021. The prevalence was highest in the WHO Western Pacific Region and lowest in the African Region and Eastern Mediterranean Region. At the country level, the prevalence was highest in high- and middle-income countries and lowest in low-income countries (3). In children, the typical age at onset of paediatric psoriasis is between 8 and 11 years (4, 5). Patients with psoriasis have a reduced quality of life that is similar to or worse than those with other chronic diseases (6, 7). Studies have reported that patients with psoriasis also have a higher risk of death compared with individuals without the disease (8–10). In a 2020 consensus statement from the International Psoriasis Council, patients with psoriasis are candidates for systemic therapy if they meet one or more of the following criteria: the disease affects > 10% of the body surface area; the disease involves special body areas (face, palms, soles, genitalia, scalp or nails); and topical therapy has failed for the patient (11). Treatment of psoriasis usually extends over the life of the patient and can involve topical therapies, systemic therapies and phototherapy, used either individually or in combination.

Bénéfices

Short-term efficacy studies (up to 24 weeks) A 2023 Cochrane living systematic review and network meta-analysis of 179 randomized controlled trials (62 339 participants) compared benefits and harms of non-biological systemic agents, small molecules and biologics in adults older than 18 years with moderate-to-severe plaque psoriasis. The review provided a ranking of treatments according to their benefits and harms (12). The included trials compared systemic treatments with placebo or active comparators. Patients had an average age of 44.6 years and a mean baseline Psoriasis Area and Severity Index (PASI) score of 20.4. The primary efficacy outcome was the proportion of participants who achieved clear or almost clear skin (PASI 90) at induction phase (8 to 24 weeks after randomization). Secondary efficacy outcomes included the proportion of participants who achieved PASI 75, and the proportion of participants who achieved a physician global assessment value of 0 or 1 at induction phase. All interventions were superior to placebo for achieving PASI 90, with the most effective treatment being infliximab (risk ratio (RR) 49.16, 95% confidence interval (CI) 20.49 to 117.96; high-certainty evidence). In absolute terms, 934 more patients per 1000 would achieve PASI ≥ 90. For the other TNF-alpha inhibitors proposed in the application, results versus placebo were: adalimumab RR 16.13 (95% CI 13.65 to 19.06; high-certainty evidence); certolizumab pegol RR 12.16 (95% CI 8.87 to 16.68; moderate-certainty evidence); and etanercept RR 9.66 (95% CI 8.14 to 11.48; moderate-certainty evidence). In absolute terms, these results correspond to 306, 234 and 184 more patients per 1000 achieving PASI ≥ 90, respectively (12). For achieving PASI 90, infliximab was significantly superior to adalimumab (RR 3.05, 95% CI 1.26 to 7.40; high-certainty evidence), certolizumab pegol (RR 4.04, 95% CI 1.60 to 10.19; moderate-certainty evidence) and etanercept (RR 5.09, 95% CI 2.10 to 12.33; moderate-certainty evidence). Adalimumab was significantly superior to etanercept (RR 1.67, 95% CI 1.47 to 1.89; moderate-certainty evidence). No significant difference was found between adalimumab and certolizumab pegol (RR 1.33, 95% CI 0.98 to 1.79; moderate-certainty evidence) (12). In comparisons of TNF-alpha inhibitors with interleukin (IL) 12/23 and 23 inhibitors, infliximab was significantly superior to ustekinumab (RR 2.84, 95% CI 1.17 to 6.87; moderate-certainty evidence) and tildrakizumab (RR 2.89, 95% CI 1.16 to 7.20; high-certainty evidence). Ustekinumab was significantly superior to certolizumab pegol (RR 1.43, 95% CI 1.06 to 1.91) and etanercept (RR 1.79, 95% CI 1.60 to 2.01) (both moderate-certainty evidence). No significant difference was seen between

ustekinumab and adalimumab (RR 1.07, 95% CI 0.98 to 1.18; moderate-certainty evidence). IL 23 inhibitors risankizumab and guselkumab were significantly superior to ustekinumab and all TNF-alpha inhibitors except infliximab. Surface under the cumulative ranking curve (SUCRA) rankings versus placebo for PASI 90 were: infliximab (first), risankizumab (fourth), guselkumab (eighth), ustekinumab (ninth), tildrakizumab (10th), adalimumab (11th), certolizumab (13th) and etanercept (15th). Results for the secondary efficacy outcomes of PASI 75 and physician global assessment 0/1 were similar to the results for PASI 90 (12). Long-term efficacy and safety studies The applicants searched the literature to identify long-term efficacy/effectiveness and safety studies on the use of adalimumab and/or ustekinumab in patients with psoriasis and identified multiple eligible studies (13–38), which were briefly summarized in Appendix 8.1 of the application. Results from selected systematic reviews and network meta-analyses are summarized below. A 2021 network meta-analysis of 14 randomized controlled trials compared efficacy (measured as PASI 75/90/100) outcomes of treatments for moderate-to-severe plaque psoriasis in adults (13). The study included regimens for IL-12/23, IL-23, IL-17 and TNF-alpha inhibitors given for 48 to 56 weeks after randomization. No risk-of-bias assessment was conducted. The proportions of participants who achieved a PASI 90 response were: 84.9% for risankizumab; 81.3% or 79.4% for bimekizumab (depending on regimen); 78.6% for brodalumab; 77.3% for guselkumab; 72.0% for ixekizumab; 66.2% for secukinumab; 55.1% for ustekinumab; 50.8% for adalimumab; and 37.4% for etanercept. Risankizumab, bimekizumab, brodalumab, guselkumab, ixekizumab and secukinumab significantly outperformed adalimumab for this outcome, whereas adalimumab was superior to etanercept. A 2022 systematic review and network meta-analysis also evaluated PASI response at 1 year of targeted therapies for moderate-to-severe plaque psoriasis in adults (36). Nine randomized controlled trials comparing eight interventions (adalimumab, brodalumab, etanercept, guselkumab, ixekizumab, risankizumab, secukinumab and ustekinumab) were included in the primary efficacy analysis. Results showed that IL-17 and IL-23 inhibitors outperformed other biological therapies for achieving PASI outcomes. In a secondary analysis of 28 randomized controlled trials, including data for apremilast, certolizumab pegol and infliximab, all therapies significantly outperformed placebo. No significant differences were seen in PASI 90 between infliximab and adalimumab (median RR 1.11, 95% CI 0.82 to 1.60), and certolizumab pegol (400 mg) and adalimumab (median RR 1.05, 95% CI 0.70 to 1.52). Both adalimumab and ustekinumab outperformed etanercept (median RR 1.30, 95% CI 1.05 to 1.78 for adalimumab and median RR 1.38, 95% CI 1.12 to 1.92 for ustekinumab). Paediatric patients A company-funded randomized, parallel group, double-blind phase III trial compared adalimumab and oral methotrexate in 114 children aged 4 to 18 years with psoriasis not responsive to topical treatment (39). Patients were randomized to receive adalimumab 0.8 mg/kg (n = 38), adalimumab 0.4 mg/kg (n = 39) or methotrexate (n = 37). Primary efficacy endpoints were the proportions of patients achieving PASI 75 and physician global assessment 0/1 at week 16. A significant difference was found favouring adalimumab 0.8 mg/kg over methotrexate in the proportion of patients who achieved PASI 75 (57.9% versus 32.4%; P = 0.027) but not physician global assessment 0/1 (60.5% versus 40.5%; P = 0.08). PASI 75 and physician global assessment 0/1 responses were reported in 43.6% and 41.0%, respectively, of patients in the adalimumab 0.4 mg/kg group. Observational studies The application presented summaries of several observational studies that support longer-term efficacy and quality-of-life outcomes of adalimumab (40–46).

Torts

In the 2023 Cochrane living systematic review and network meta-analysis, the primary safety outcome was the proportion of participants with serious adverse events (death, life-threatening events, initial or prolonged hospitalizations and adverse events requiring intervention to prevent permanent impairment or damage) at the induction phase (12). No significant differences were seen between active interventions versus placebo in the risk of serious adverse events. Considering TNF-alpha inhibitors IL-12-23 and IL-23 inhibitors SUCRA rankings versus placebo for serious adverse events were: risankizumab (third), certolizumab (fifth), etanercept (sixth), tildrakizumab (eighth), guselkumab (11th), ustekinumab (13th), adalimumab (14th) and infliximab (19th). In the 2023 network meta-analysis, rates of adverse events for the various treatments investigated were 37.5% for risankizumab, 72.2% for guselkumab, 72.9% for adalimumab, 76.6% for secukinumab, 76.9% for ustekinumab, 80.9% for ixekizumab and 82.3% for bimekizumab (13). Risankizumab had a significantly lower rate of adverse events than secukinumab, ustekinumab and bimekizumab. Rates of serious adverse events at week 48–56 were 4.4% for risankizumab, 5.4% for adalimumab, 5.7% for ustekinumab, 5.9% for guselkumab, 6.9% for secukinumab, 7.2% for bimekizumab and 10.5% for ixekizumab. No significant difference was seen between treatments for serious adverse events. Treatment with TNF-alpha inhibitors has been associated with an increased risk of serious infections. Real-world registry data studies have reported a higher risk with adalimumab and infliximab compared with non-methotrexate and non-biologic therapies (25), but no increased risk compared to methotrexate or other biologic therapies (19, 37). TNF-alpha inhibitor treatment has also been associated with an increased risk of reactivation of latent tuberculosis (17, 32). Treatment with TNF-alpha inhibitors has also been associated with a slightly increased long-term risk

of malignancy, particularly non-melanoma skin cancer in patients with psoriasis compared with non-biologic therapy. However, the evidence is mixed with some studies showing an elevated risk (22, 31), and others showing no association (29).

Rapport coût/efficacité

The application identified and summarized the findings of 11 published economic analyses comparing biologic therapies for moderate-to-severe plaque psoriasis (47–56). Publication dates ranged from 2013 to 2023, with the studies conducted primarily in health-care systems of high-income countries. Comparisons, time horizons and willingness-to-pay thresholds differed across the studies, but generally, adalimumab was found to be a cost-effective treatment option. Comparative cost information for adalimumab in different markets was not available.

Directives de l'OMS

WHO guidelines for the treatment of psoriasis are not currently available.

Disponibilité

Adalimumab has wide global regulatory approval and market availability and is already included on many national essential medicines lists for other indications. Biosimilar versions have been available since 2016 and potential price reductions of up to 80% have been reported compared with the innovator brand (57). Among the available TNF-alpha inhibitors, infliximab biosimilars are currently the most widely disseminated option in several low- and middle-income countries and are generally associated with lower prices compared to originator products.

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