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Subject Medicine Reimbursement System advice for amisulpride (Aktiprol®)

National Health Care Institute

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Infectious Diseases, Blood & Immunology

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Dear Ms van Ark,

In your letter of 7 September 2020 (CIBG-20-0910), you asked the National Health Care Institute to assess whether the product amisulpride (Aktiprol®) can be included in the Medicine Reimbursement System (hereinafter the "GVS") by means of a marginal review. The considerations are included in the GVS report attached to this letter.

Conclusion of the marginal review

Based on the criteria for interchangeability, it can be concluded that amisulpride (Aktiprol®) is interchangeable with the other medicinal products in the GVS cluster group 4N05***O V, which includes aripiprazole (Abilify®), cariprazine (Reagila®), lurasidone (Latuda®), olanzapine (Zyprexa®), paliperidone (Invega®), quetiapine (Seroquel®), risperidone (Risperdal®), sertindole (Serdolect®) and sulpiride (Dogmatil®). The defined daily dose (DDD) for amisulpride has been set by the World Health Organization (WHO) at 400 mg. The DDD is within the dose range stated in the text of the licence. The standard dose can therefore be set to 400 mg.

Advice

We advise you to include amisulpride (Aktiprol®) in the GVS on List 1A in cluster group 4N05***O V. 400 mg can be used as the standard dose. Amisulpride (N05AL05) has an ATC code that is comparable to that of sulpiride (N05AL01).

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board