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TRANSPARENCY COMMITTEE
Opinion
3 October 2012

CONCERTA LP 18 mg, prolonged-release tablets

B/28 (CIP code: 34009 361 554 1 1)

CONCERTA LP 36 mg, prolonged-release tablets

B/28 (CIP code: 34009 361 555 8 9)

CONCERTA LP 54 mg, prolonged-release tablets

B/28 (CIP code: 34009 361 556 4 0)

Applicant: JANSSEN-CILAG

INN	Methylphenidate
ATC Code (2012)	N06BA04 (psychostimulants)
Reason for the review	Re-assessment of methylphenidate-based proprietary products in attention-deficit hyperactivity disorder in response to a request from the Directorate-General for Health
Lists concerned	National Health Insurance (French Social Security Code L.162-17)
Indications concerned	Attention-deficit hyperactivity disorder in children aged six years and over when remedial measures alone prove insufficient.

01 COMMITTEE CONCLUSIONS

The Committee has re-assessed the actual benefit of proprietary products containing methylphenidate and the conditions of use of these products in attention-deficit hyperactivity disorder (ADHD) in response to a request from the Directorate-General for Health of 22 May 2012.
The report of the Transparency Committee is appended.

Its conclusions as to the actual benefit of methylphenidate in the indication “ADHD in children aged 6 years and over when remedial measures alone prove insufficient” are as follows:

ADHD is defined mainly by signs of lack of attention, hyperactivity and impulsivity. It may occur alongside other disorders such as oppositional defiant disorder, learning disability, anxiety, depression, tic disorder and Tourette syndrome. ADHD may lead to substantial impairment of interpersonal relationships and performance at school.

Methylphenidate-based proprietary products fall under the category of symptomatic treatment.

The efficacy/safety ratio for these medicinal products is moderate.

Management of ADHD is comprehensive. It comprises primarily psychological, educational and social measures which, if they really prove insufficient, can be combined with methylphenidate, as second line therapy.

There are several methylphenidate-based proprietary products.

Public health benefit

In view of its prevalence, estimated to be 2% in the case of school-age children¹, and the impact it has on family, education and social circles, the public health burden of attention-deficit hyperactivity disorder may be considered to be moderate.

Improving the treatment of children with this disorder, frequently combined with other concomitant disorders (language disturbances, psychiatric disorders, sleep disorders etc.) is a public health need which is an established priority (French 2004 Law on Public Health, French Psychiatry and Mental Health Plan).

The response to this need should not be restricted to a drug-related approach (psychological, educational and family-based measures should also be instituted). When drug treatment is recommended, methylphenidate-based medicinal products help meet the public health need identified.

In view of the available data these proprietary products can be considered to have a low impact in terms of morbidity, quality of life and socio-educative effect for the patients treated.

Moreover, it is not certain that clinical trials can be transposed into practice, owing to the remaining uncertainties about the medium- and long-term effects of methylphenidate, particularly in terms of cardiovascular, neurological and psychiatric events.

There is a risk of inappropriate use, misuse or abuse of methylphenidate.

Consequently, in the light of current knowledge, methylphenidate-based proprietary products offer a public health benefit in this indication. This benefit is slight.

¹ Troubles mentaux : Dépistage et prévention chez l'enfant et l'adolescent. Expertise collective INSERM. Les Editions INSERM 2002

The Transparency Committee considers that:

The actual benefit of CONCERTA LP proprietary products is substantial in the context of the overall therapeutic management of ADHD in children aged 6 years and over when psychological, educational and social management alone prove insufficient.

The Committee points out that prescriptions for methylphenidate must comply strictly with the indication authorised by the MA and should be restricted to ADHD, to the exclusion of other behavioural disorders. Diagnosis should be made according to DSM-IV criteria or the guidelines in ICD-10 and should be based on a complete history and evaluation of the child. The Committee notes the undesirable effects of methylphenidate and is still concerned about its long-term effects, linked to its amphetamine-like structure.

The Transparency Committee recommends continued inclusion on the list of medicines refundable by National Health Insurance in the indications in the Marketing Authorisation.

► **Proposed reimbursement rate: 65%**

02 COMMITTEE RECOMMENDATIONS

As a consequence of its conclusions, the Transparency Committee recommends that information resources on methylphenidate be produced for patients, families and healthcare professionals.

► **Packaging**

Methylphenidate comes under narcotics regulations.

The packaging of CONCERTA LP 18 mg, 36 mg, 54 mg (B/28) is unsuitable: the tablets/hard capsules are packed in a bottle containing one or two desiccants in direct contact with the contents and closed with a “child-resistant” cap. This bulk packaging does not allow the guaranteed preservation, safety and appropriate identification of the medicinal product if removed from the packaging.

This opinion is available on the site of the Haute Autorité de Santé.
<http://www.has-sante.fr>