HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

TRANSPARENCY COMMITTEE

Opinion

3 October 2012

QUASYM LP 10 mg, modified release capsule

B/28 (CIP code: 34009 497 261 6 5)

QUASYM LP 20 mg, modified release capsule

B/28 (CIP code: 34009 497 262 2 6)

QUASYM LP 30 mg, modified release capsule

B/28 (CIP code: 34009 497 267 4 5)

Applicant: SHIRE

INN	Methylphenidate
ATC Code (2010)	N06BA04 (psychostimulants)
Reason for the review:	**Reassessment of medicines containing methylphenidate in attention deficit hyperactivity disorder in response to the instruction from the Directorate-General for Health**
Lists concerned	**Social Security (CSS L.162-17)**
Indications concerned	**Attention deficit hyperactivity disorder in children aged six years old 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 integration at school.

Methylphenidate-based proprietary products fall within 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 children[1], 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 implemented). When drug treatment is recommended, methylphenidate-based medicinal products help to meet identified need for public health.
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 treated patients.
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 QUASYM LP proprietary products is substantial in the context of the overall therapeutic management of ADHD in children aged 6 years old 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, excluding 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 educational tools on methylphenidate be produced for patients, families and healthcare professionals.

◗ Packaging
Methylphenidate comes under the narcotics regulations. The packaging for QUASYM LP is appropriate.

This opinion is available on the Haute Autorité de santé website;
http://www.has-sante.fr