HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

TRANSPARENCY COMMITTEE

OPINION

21 July 2010

EXTAVIA 250 microgram/ml, powder and solvent for solution for injection
B/15 (CIP code: 386 554-5)

Applicant: NOVARTIS PHARMA S.A.S.

interferon beta-1b
ATC code: L03AB08

List I
Exception drug status
Medicine requiring special monitoring during treatment.
Medicine requiring prescription initiation and renewal by neurology specialists only.

Date of Marketing Authorisation: 20 May 2008
A Marketing Authorisation for EXTAVIA was issued with the consent of Bayer Schering authorising Novartis to refer to the Marketing Authorisation for BETAFERON 250 µg/mL, powder and solvent for solution for injection (article 10c of EC Directive 2001/83/EC).

Reason for request: Re-assessment of the improvement in actual benefit (IAB) of beta interferons and glatiramer acetate indicated in multiple sclerosis.

Therapeutic indications:

"Extavia is indicated for the treatment of:

• Patients with a single demyelinating event with an active inflammatory process, if it is severe enough to warrant treatment with intravenous corticosteroids, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis.

• Patients with relapsing-remitting multiple sclerosis and two or more relapses within the last two years.

• Patients with secondary progressive multiple sclerosis with active disease, evidenced by relapses."

Dosage: see SPC
The transparency Committee has reassessed beta interferons and glatiramer acetate in multiple sclerosis. Available clinical data and experience of beta interferons in multiple sclerosis in everyday practice since their commercialization do not make it possible to differentiate between them in terms of actual benefit and improvement in actual benefit (IAB). According to the enclosed report, the Committee concluded:

Actual benefit

Multiple sclerosis is an incapacitating, progressive, chronic neurological disorder. It involves the selective, chronic inflammation and demyelinisation of the central nervous system. Disability comes in many forms, depending on the progression of the disease and the individuals: motor and sensory disorders, sensory, bladder-sphincter system, sexual deficits, cognitive dysfunction and mood disorders. These disorders may considerably reduce patients' autonomy and impair their quality of life.
The disease varies considerably in severity, with benign forms which cause very little disability and severe forms which lead to major disability within a few years.

EXTAVIA is a medicinal product intended to prevent acute exacerbations and progression of disability.

The efficacy of the medicinal product is relatively modest: the frequency of acute exacerbations is decreased by 30% and progression of disability is slightly slowed in the short term. Efficacy against long-term progression of disability remains unclear and no criteria for discontinuing treatment have been established, but its tolerance profile is acceptable. It has a high efficacy/adverse effects ratio.

Alternative medicinal products exist.

Public health benefit:

> The public health burden of MS is moderate. Improvement in the treatment of MS is a public health need which is an established priority (French 2004 Law on Public Health).
> In view of the available data, the medicinal product EXTAVIA has an impact on morbidity (frequency of acute exacerbations). This impact is low. The medicinal product therefore provides a partial response to an identified public health need.
> The public health benefit contributed by EXTAVIA in MS is therefore weak.

The actual benefit of this medicinal product remains substantial.

Improvement in actual benefit:

The medicinal product EXTAVIA does not provide any improvement in actual benefit (level V) compared with BETAFERON in the treatment of patients with multiple sclerosis.

Packaging: appropriate for the prescription conditions.

Reimbursement level: 65%