HAUTE AUTORITÉ DE SANTÉ

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TRANSPARENCY COMMITTEE

Opinion
28 May 2014

PHYSIOGINE 1 mg, scored tablet
B/1 Blister of 30 tablets (CIP: 3400933826345)

Applicant: HAC PHARMA

INN	estriol
ATC code (2013)	G03CA04 (oestrogen)
Reason for the review	**Re-assessment of the Actual Benefit of all medicines indicated for menopausal hormone replacement therapy at the request of the Committee, pursuant to Article R-163-21 of the French Social Security Code**
Lists concerned	**National Health Insurance (French Social Security Code L.162-17)** **Hospital use (French Public Health Code L.5123-2)**
Indication concerned	**'Correction of symptoms related to oestrogen deficiency during natural or artificial premature or secondary ovarian failure, when used as a short-term treatment. '**

01 ADMINISTRATIVE AND REGULATORY INFORMATION

Marketing Authorisation	14 June 1995 (national procedure)
Prescribing and dispensing conditions	List II

02 TRANSPARENCY COMMITTEE CONCLUSIONS

Based on the assessment report attached to this opinion, the Committee considered that:

02.1 ACTUAL BENEFIT

Correction of symptoms related to oestrogen deficiency during natural or artificial premature or secondary ovarian failure, when used as a short-term treatment.

◗ Vasomotor symptoms of menopause when they are frequent and intense may significantly impair quality of life.

◗ This proprietary medicinal product is intended as symptomatic therapy.

◗ The efficacy/adverse effects ratio is modest in patients with climacteric disorders that are described as bothersome enough to impair their quality of life and in compliance with the Committee's recommendations.

◗ There are numerous treatment alternatives (other hormonal treatments for menopause).

◗ PHYSIOGYNE 1 mg, scored tablet is a first-line therapy for climacteric disorders when they are bothersome enough to impair quality of life.

◗ Public health benefit

At the time of menopause, in the general population, the proportion of women complaining of climacteric disorders is supposedly more than 50%.[1] The most common symptom is hot flashes; approximately one in three women present with night sweats. However, there may be other symptoms: vaginal dryness or urinary symptoms. The frequency and severity of these symptoms decrease with time but are still present 10 years after menopause in approximately one out of four women.

As a result, given the limitations of their use in menopausal women, HRTs have little impact on public health.

Consequently, the Committee considers that the actual benefit of the proprietary medicinal product PHYSIOGYNE 1 mg, scored tablet remains moderate in the indication in the Marketing Authorisation, in patients for whom climacteric disorders are described as bothersome enough to impair their quality of life, when these proprietary medicinal products are used as per the Committee's recommendations.

[1] ANAES [National Health Accreditation and Assessment Agency]/ANSM [French National Agency for Medicines and Health Products Safety] Traitements hormonaux substitutifs de la ménopause. Rapport d'orientation, 11 May 2004

03 TRANSPARENCY COMMITTEE RECOMMENDATIONS

The Committee recommends:

- Carefully weighing the benefit of hormone therapy against the symptoms and their impact on the patient's quality of life.
- Prescribing these treatments in accordance with their contraindications, in particular concerning the risk of thromboembolism and breast cancer.

These treatments should be prescribed when the climacteric disorders are described by the patient as troublesome enough to impair their quality of life, at the lowest effective dose, for the shortest duration possible as per the AFSSAPS's guidelines (see the appendix), in particular:

- before initiating or reinstituting HRT, a complete clinical and gynaecological examination (including an analysis of the family history) should be performed. A regular breast examination should be performed as per the current recommendations (palpation, mammography, ultrasound, etc.) and tailored to individual cases.
- at the start of treatment, patients must be given all relevant information enabling an appropriate and informed prescription. Thus, patients must be informed of the risks inherent to the treatment. In addition, the treatment should be re-assessed regularly, at least once a year, taking into account changes in the benefit/risk ratio. The treatment may be temporarily suspended during this reassessment in order to verify the persistence of the climacteric syndrome and its severity.

The Committee recommends continued inclusion on the list of medicines refundable by National Health Insurance and on the list of medicines approved for hospital use in the indication in the Marketing Authorisation and as recommended by the Committee.

◗ **Proposed reimbursement rate: 30%**