HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

TRANSPARENCY COMMITTEE

Opinion

28 May 2014

LUTENYL 3.75 mg, tablet

B/1 blisters of 14 tablets (CIP: 3400936557246)

LUTENYL, scored tablet

B/1 blisters of 10 tablets (CIP: 3400932661121)

Applicant: TEVA Santé

INN	Nomegestrol acetate
ATC Code (2013)	G03DB04 (progestin)
Reason for the review	**Reassessment of the Actual Benefit of all medicines indicated in hormone replacement therapy for the menopause 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)
Indications concerned	**LUTENYL 3.75 mg** **"In combination with an oestrogen within the framework of hormone replacement therapy (HRT) in non-hysterectomised postmenopausal women."** **LUTENYL** **"In postmenopausal women: artificial cycles in combination with an oestrogen."**

01 ADMINISTRATIVE AND REGULATORY INFORMATION

Marketing Authorisation	LUTENYL 3.75 mg: 10 September 2004 (national procedure) 5 mg: 18 November 1983 (national procedure)
Prescribing and dispensing conditions	List I

02 TRANSPARENCY COMMITTEE CONCLUSIONS

According to the assessment attached to this opinion, the Committee found that:

02.1 ACTUAL BENEFIT

LUTENYL: in postmenopausal women, artificial cycles in combination with an oestrogen;
LUTENYL 3.75 mg: in combination with an oestrogen within the framework of hormone replacement therapy (HRT) in non-hysterectomised postmenopausal women.

◗ Endometrial hyperplasia increases the risk of endometrial cancer.

◗ These proprietary medicinal products are preventive treatments.

◗ The efficacy/adverse effects ratio is high.

◗ Combination of progestin treatment with oestrogen treatment is recommended in non-hysterectomised women to avert the risk of endometrial hyperplasia that is consequent upon oestrogen treatment on its own. There are treatment alternatives: other progestin treatments.

◗ These medicinal products are first-line therapies.

◗ Public health benefit:
Progestins are only indicated in the hormonal treatment of the menopause in non-hysterectomised women to avert the risk of endometrial hyperplasia that is consequent upon oestrogen treatment on its own.
Thus, in combination with oestrogen treatment, they have the same impact on public health in each of the two indications for hormonal treatment of the menopause as proprietary medicinal products that combine an oestrogen and a progestin.
The benefit in the treatment of the symptoms of oestrogen deficiency is low and there is no benefit in the prevention of postmenopausal osteoporosis.

Consequently, the Committee considers that the actual benefit of the proprietary medicinal products LUTENYL remains substantial in the indication "in postmenopausal women, artificial cycles in combination with an oestrogen" and that of LUTENYL 3.75 mg remains substantial in the indication "in combination with an oestrogen within the framework of hormone replacement therapy (HRT) in non-hysterectomised postmenopausal women" in non-hysterectomised postmenopausal women and within the limits defined for the use of the oestrogen treatment with which it is combined when the proprietary medicinal products are used in accordance with the recommendations of the Committee.

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.

In the prevention of postmenopausal osteoporosis in women at increased risk of osteoporotic fracture and who are intolerant to, or contraindicated for, the other treatments indicated for the prevention of osteoporosis, these treatments should be prescribed in the event of climacteric disorders and recent menopause, after a minor fracture or if there is a low T-score.

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 of the proprietary medicinal product LUTENYL in the indication "in postmenopausal women, artificial cycles in combination with an oestrogen" and of the proprietary medicinal product LUTENYL 3.75 mg in the indication "in combination with an oestrogen within the framework of hormone replacement therapy (HRT) in non-hysterectomised postmenopausal women" and in accordance with the recommendations of the Committee.

◗ **Proposed reimbursement rate: 65%**