HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
18 SEPTEMBER 2019

naftidrofuryl
PRAXILENE 100 mg, capsules
PRAXILENE 200 mg, film-coated tablets

Reassessment

Key points

Negative opinion to maintenance of reimbursement in the symptomatic treatment of intermittent claudication of obliterating chronic arterial disease of the lower limbs (stage 2)

Actual benefit now insufficient (previously low)

Role in the care pathway?

Treatment of intermittent claudication is based on a walking training program, preferably supervised, in addition to dietary and lifestyle measures, management of cardiovascular risk factors (smoking, hypertension, dyslipidemia, diabetes) and prevention of cardiovascular complications. Statin therapy is recommended, in addition to general prevention, to improve walking distance. Revascularisation must be considered in the case of alterations in daily activities, despite the physical exercise therapy, or immediately in combination with physical exercise therapy when the symptoms considerably affect daily activities.

Role in the care pathway:

Considering:

- **the modest efficacy and low clinical relevance of naftidrofuryl compared to placebo, demonstrated only on a symptomatic endpoint - pain-free walking distance - in several old clinical trials that do not correspond to current care conditions, ,**
- **the safety profile of this medicinal product, with the occurrence of cases of serious liver damage, such as acute cytolytic hepatitis,**

PRAXILENE (naftidrofuryl) no longer has a role in the care pathway for the management of intermittent claudication in arterial disease of the lower limbs.

Special recommendations

Following the Committee's negative opinion to the reimbursement of proprietary medicinal products belonging to the peripheral vasodilators class, including naftidrofuryl, in the treatment of intermittent claudication, the Committee recommends orienting patients towards a walking training program, in addition to dietary and lifestyle measures, management of cardiovascular risk factors (smoking, hypertension, dyslipidemia, diabetes) and prevention of cardiovascular complications.

COMMITTEE'S CONCLUSIONS

Actual benefit

◗ Chronic peripheral artery disease (PAD) is a serious disease, likely to lead to serious functional consequences (handicap, amputation, loss of autonomy) and a significant impact on quality-of-life.

◗ PRAXILENE is part of a symptomatic treatment.

◗ Given the modest effect and low clinical relevance of naftidrofuryl demonstrated versus placebo on pain-free walking distance, regarding the occurrence of severe liver damage, the naftidrofuryl efficacy/adverse effects ratio is insufficient.

◗ There are therapeutic alternatives.

◗ The committee considers that naftidrofuryl no longer has a role in the therapeutic strategy for the management of intermittent claudication of obliterating chronic arterial disease of the lower limbs.

◗ Public health benefit
According to the current knowledge, the previous assessment of the PHB is not modified: PRAXILENE is not likely to have an additional impact on public health.

Considering all these elements, the Transparency Committee deems that the actual benefit of PRAXILENE is insufficient to justify reimbursement by national solidarity in the MA indication and dosages.

Clinical Added Value

Not applicable.