HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

TRANSPARENCY COMMITTEE

OPINION

5 January 2011

REMODULIN 1 mg/ml, solution for infusion (subcutaneous route)
20-ml glass vial (CIP code: 368 161-5)
REMODULIN 2.5 mg/ml, solution for infusion (subcutaneous route)
20-ml glass vial (CIP code: 368 162-1)
REMODULIN 5 mg/ml, solution for infusion (subcutaneous route)
20-ml glass vial (CIP code: 368 163-8)
REMODULIN 10 mg/ml, solution for infusion (subcutaneous route)
20-ml glass vial (CIP code: 368 164-4)

Applicant: BIOPROJET PHARMA

treprostinil sodium
ATC code: B01AC21

List I
Medicine for hospital prescription only, restricted to specialists and/or departments specialising in pneumology or cardiology.

Date of Marketing Authorisation (by mutual recognition): 28 February 2005

Reason for examination: Reassessment of actual benefit and improvement in actual benefit under article R-163-21 of the Social Security Code.

Indications:
“Treatment of primitive pulmonary arterial hypertension (PAH) to improve exercise capacity and symptoms of the disease in patients in NYHA (New York Heart Association) functional class III.”

Dosage: see SPC

The Transparency Committee has reassessed all treatments for PAH. Distinctions have been drawn between the various proprietary drugs (see complete report attached).
The Transparency Committee’s conclusions regarding REMODULIN were as follows:

Actual benefit

PAH is a rare pulmonary condition that affects life expectancy. It is characterised by gradual blocking of the small pulmonary arteries, leading to a gradual increase in pulmonary arterial pressure and right cardiac insufficiency. PAH is defined by an increase in mean pulmonary arterial pressure (mPAP) measured by cardiac catheterisation which is equal to or greater than 25 mmHg at rest, with no increase in pulmonary capillary pressure. Asthenia, dyspnoea, chest pain, and loss of consciousness are the most frequent clinical signs. Median survival under symptomatic treatment is around 2.5 years for patients with functional class III PAH and is 4.8 years.

All treatments for PAH are symptomatic.

The efficacy/adverse effects ratio is moderate.

In practice, prostacyclins are used as second-line treatment.

No public health benefit is expected.

The actual benefit is moderate.

Improvement in actual benefit (IAB)

The Transparency Committee is of the opinion that the REMODULIN range of proprietary drugs provides a minor improvement in actual benefit (IAB IV) in the treatment of idiopathic pulmonary arterial hypertension for patients in functional class III.

Medical, Economic and Public Health Assessment Division