HAUTE AUTORITÉ DE SANTÉ

NEUROLOGY
New indication
December 2017

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

CLAIRYG, human immunoglobulin

Substantial clinical benefit in the treatment of chronic inflammatory demyelinating polyneuropathy, but no clinical benefit demonstrated compared with immunoglobulins (OCTAGAM, TEGELINE and PRIVIGEN)

Main points

- CLAIRYG already has Marketing Authorisation in the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP).
- The Marketing Authorisation in this indication was obtained based on the results (descriptive only) of a phase III study comparing CLAIRYG and TEGELINE.
- The use of immunoglobulin administered intravenously (IVIGs) is well documented in the treatment of CIDP. The role of CLAIRYG in the therapeutic strategy is similar to that of these other immunoglobulins.

Pre-existing indications*

CLAIRYG also has Marketing Authorisation as an immunomodulator treatment and replacement therapy.

Therapeutic use

- Intravenous human immunoglobulins are, alongside corticosteroid therapy and plasma exchange, a first-line treatment for CIDP.
  - The initial treatment depends on the clinical presentation:
    - for mild symptoms and moderate disability, monitoring without treatment is recommended.
    - for sensory motor involvement leading to moderate to severe disability, IVIGs and corticosteroids are used as a first-line treatment.
    - for the pure motor form, IVIGs are used alone; corticosteroids may worsen neurological involvement.
    - in case of failure of IVIGs or corticosteroid therapy: plasma exchange may also be prescribed.
  - When one of these treatments is effective, it is continued until maximum benefit is obtained and then as maintenance treatment, where the IVIG dose will be reduced to the minimum effective dose and the corticosteroid dose will be reduced very gradually over 1 to 2 years, down to the minimum effective dose.
  - If the response to IVIGs or corticosteroids is insufficient, or if the maintenance doses are too high, the addition of an immunomodulator can be considered, but none has been validated in a comparative study in CIDP.

- **Role of the medicinal product in the therapeutic strategy**

  CLAIRYG can be prescribed to patients with CIDP alongside other IVIGs. However, its clinical efficacy has been quantified (INCAT scale) only in maintenance treatment in 19 patients treated with IVIG for at least 6 months and for whom the minimum effective dose of IVIG had been determined.

Clinical data

- CLAIRYG was assessed in CIDP in a randomised, double-blind, comparative study versus TEGELINE in 39 patients (19 patients in the CLAIRYG group and 20 patients in the TEGELINE group), treated with IVIG for at least 6 months and for whom the minimum effective dose of IVIG had been determined. The results of this study are only descriptive given the small number of patients included, which does not allow a statistical comparison with sufficient power. During this period, patients received on average 4 cycles over a mean duration of exposure

* This summary does not cover these indications.

© Haute Autorité de Santé 2018

of 24 weeks with a mean dosage per cycle of 1.5 g/kg. The efficacy (response to treatment) was assessed using the INCAT disability score (score of 0 [no disability] to 5 [maximum disability] for the lower and upper limbs, i.e. a total score of 0 to 10). The primary efficacy endpoint was the proportion of patients with no relapse throughout the 6-month follow-up, defined as the patients whose adjusted INCAT disability score (disability scale for only the upper limbs, after exclusion of subjective symptoms, leading to a total score between 0 and 4) remained the same as at baseline or increased by one point without “reinforcement in treatment” for CIDP. The response rate was 94.7% (18/19) in the CLAIRYG group versus 92.3% (18/20) in the TEGELINE group, suggesting a similar efficacy in both groups.

- The other data obtained in CIDP concern other IVIGs. They show a greater clinical improvement with IVIGs than with placebo, but do not show the specific efficacy of CLAIRYG.

Special prescribing conditions

- Blood-derived medicinal product for hospital prescription and only authorised for physicians practising at a blood transfusion facility authorised to dispense medicinal products to patients treated there.

Benefit of the medicinal product

- The actual benefit* of CLAIRYG is substantial in CIDP.
- CLAIRYG does not provide clinical added value** (CAV V) in the treatment of chronic inflammatory demyelinating polyneuropathy by comparison with immunoglobulins (OCTAGAM, TEGELINE and PRIVIGEN).
- Recommends inclusion on the list of reimbursable products for hospital use.

HAUTE AUTORITÉ DE SANTÉ
This document was created on the basis of the Transparency Committee Opinion of 06 December 2017 (CT-16502) and is available at **www.has-sante.fr**

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means “no clinical added value”.

© Haute Autorité de Santé 2018