HAUTE AUTORITÉ DE SANTÉ

ONCOLOGY
NEW PRESENTATION
October 2016

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

NEOFORDEX (dexamethasone), glucocorticoid

Minor clinical added value for this medicine based on dexamethasone at 40 mg compared to DECTANCYL (dexamethasone 0.5 mg) in the context of symptomatic multiple myeloma therapeutic protocols

Main points

- NEOFORDEX has marketing authorisation for adults, in combination, for the treatment of symptomatic multiple myeloma.
- The use of corticosteroid therapy has been established for many decades in haematological malignancies and especially multiple myeloma.
- The dexamethasone form of NEOFORDEX 40 mg is more suitable than the 0.5 mg form.

Therapeutic use

- The use of corticosteroid therapy has been established for many decades in haematological malignancies and, especially, multiple myeloma.
- **Role of the proprietary medicinal product in the therapeutic strategy**
  NEOFORDEX 40 mg has had an established role for many years for dexamethasone in the treatment of multiple myeloma.

Clinical data

- No clinical efficacy and safety study has been carried out specifically with the proprietary medicinal product NEOFORDEX 40 mg in the treatment of multiple myeloma.
- A pharmacokinetic study in 24 healthy subjects allowed establishing bioequivalence of the dose of 20 mg of oral dexamethasone dispensed as a half tablet of NEOFORDEX 40 mg versus DECTANCYL 0.5 mg tablet (dexamethasone) at the same dosage.
- The efficacy and safety of multiple therapies including dexamethasone in multiple myeloma have been confirmed in many clinical studies dating back many decades and since confirmed by multiple studies in patients with an untreated or relapsed or refractory myeloma. The patient populations studied covered a broad range of ages, and included patients considered eligible or non-eligible for an autologous stem cell graft. High dose oral dexamethasone (40 mg or 20 mg) has been studied in the treatment of multiple myeloma in combination with chemotherapy under the VAD protocol (vincristine, adriamycin/doxorubicin and dexamethasone), or in combination with new therapeutic agents, including thalidomide and its analogues as well as proteasome inhibitors. In controlled studies, multiple therapy combining dexamethasone has systematically given better results in terms of survival and response than dexamethasone as a monotherapy.

Special prescribing conditions

- Prescription restricted to specialists in oncology or haematology, and to doctors competent in cancerology and blood diseases.
- Medicinal product requiring special monitoring during treatment.

Benefit of the medicinal product

- The actual clinical benefit* of NEOFORDEX is substantial.
- Given the reduction in the number of administrations compared to DECTANCYL (dexamethasone 0.5 mg), even though this reduction in the number of administrations has not demonstrated clinical benefit, NEOFORDEX 40 mg provides a minor clinical added value (CAV IV) relative to DECTANCYL in the context of symptomatic multiple myeloma therapeutic protocols.
- Recommends inclusion on the list of reimbursable products for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 19 October 2016 (CT-15218) and is available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a 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 ACB, which can be substantial, moderate, low or insufficient for reimbursement of the medicinal product 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 (equivalent to “no CAV”) means “no clinical added value”.