SUMMARY

dupilumab

DUPIXENT 300 mg,

solution for injection in pre-filled syringe or pre-filled pen

New indication

Adopted by the Transparency Committee 22 mars 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion on reimbursement in "the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy".

What therapeutic improvement ?

Therapeutic improvement in the management strategy.

Role in the care pathway?

DUPIXENT 300 mg (dupilumab), solution for injection in pre-filled syringe or pre-filled pen, is a first-line systemic treatment for moderate-to-severe prurigo nodularis in adults which requires systemic treatment.

Specific recommendations?

The Committee recommends exception drug status for DUPIXENT (dupilumab) in this extension of indication.

Transparency Committee's Conclusions

Clinical Benefit

- Moderate-to-severe prurigo nodularis is a serious chronic disease, that is rare and very disabling, marked by a significant deterioration in patients' quality of life.
- DUPIXENT 300 mg (dupilumab), solution for injection in pre-filled syringe or pre-filled pen, is a symptomatic medicinal product.
- The efficacy/adverse effect ratio is significant.
- It is a first-line systemic treatment, in adult patients with moderate-to-severe prurigo nodularis which requires systemic treatment.
- There are no validated alternatives. The alternatives available in the event that local treatments and phototherapy fail are used off-label, have a low level of proof, and have significant adverse effects that do not allow prolonged use.

Public health benefit

Considering:

- the gravity of the disease and its low prevalence (rare disease),
- the unmet medical need,
- the partial response provided to the unmet medical need identified in view:
  - an additional proven impact on morbidity and on quality of life,
  - the additional impact expected on the patient's care pathway and life course,
  - the absence of proven impact on the organisation of care,

DUPIXENT (dupilumab) is liable to have an additional impact on public health.

In view of all of these elements, the Committee considers that the clinical added value provided by DUPIXENT 300 mg (dupilumab), solution for injection in pre-filled syringe or pre-filled pen, is significant in the MA indication.

The Committee gives a favourable opinion on the inclusion of DUPIXENT (dupilumab), solution for injection in pre-filled syringe or pre-filled pen, on the list of medicinal products reimbursable to persons insured under social security schemes and on the list of medicinal products approved for the use of communities in the MA indication and at the MA doses.

Recommended reimbursement rate for inclusion on the list of medicinal products reimbursable to persons insured under social security schemes: 65 %.

Clinical Added Value

In view of:

- the unmet medical need,
- the demonstration in two phase III, randomised, double blind studies, of the superiority of dupilumab compared to placebo, with a significant and clinically relevant effect on:
  - the percentage of patients who experienced a reduction in the maximum pruritus score, WI-NRS ≥ 4 between inclusion and week 12 (LIBERTY-PN-PRIME2 study) or week 24 (LIBERTY-PN-PRIME and LIBERTY-PN-PRIME2 studies),
  - the variation in the DLQI quality of life score,
  - the variation in the Skin Pain-NRS pain score and
  - the variation in the HADS score assessing anxiety and depression (only in LIBERTY-PN-PRIME),
- but of the absence of demonstration of the superiority of dupilumab compared to placebo with regard to sleep quality, while this is strongly impacted by the symptoms of prurigo nodularis,
- a tolerance comparable to that observed in the other indications of dupilumab, marked mainly by the occurrence of rhinopharyngitis, upper airway infections, ocular disorders (conjunctivitis, keratitis, keratoconjunctivitis) and injection site reactions,

The Committee considers that DUPIXENT (dupilumab), solution for injection in pre-filled syringe or pre-filled pen, provides moderate clinical added value (CAV III) in the management of moderate-to-severe prurigo nodularis in adults which requires systemic treatment.