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ANALGESICS
New indication
February 2018

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

QUTENZA (capsaicin), local analgesic patch

Insufficient actual benefit to justify its inclusion on the list of reimbursable products for peripheral neuropathic pain in diabetic patients due to low efficacy, that is not clinically relevant, and demonstrated only versus placebo.

Main points

- QUTENZA now has Marketing Authorisation in the treatment of peripheral neuropathic pain in adults with diabetes.
- Its efficacy in these patients was assessed versus placebo. It is low and is not clinically relevant. Its efficacy has not been assessed versus other alternatives available even though this comparison was feasible.
- Its use is commonly associated with painful reactions at the application site.
- Its methods of application are restrictive and require training of the staff.

Pre-existing indications*

- QUTENZA has Marketing Authorisation in the treatment of peripheral neuropathic pain, alone or in combination with other medicinal products for pain, in nondiabetic adult patients.

Therapeutic use

- First-line drug therapies for neuropathic pain are based on the use of tricyclic antidepressants (amitriptyline, imipramine, clomipramine), serotonin-norepinephrine reuptake inhibitor antidepressants (duloxetine) or antiepileptics (gabapentin or pregabalin), the safety profile of which can limit their prescription. Tramadol is also recommended as first-line therapy when there is a strong nociceptive component associated with neuropathic pain.
- Lidocaine patches are a first-line treatment option in the treatment of pain after shingles when lesions are localised, and particularly in elderly patients with allodynia and in whom systemic treatments are contraindicated or inadvisable.
- The prescription of strong opiates is recommended in the treatment of chronic neuropathic pain of persistent high intensity after failure of first-line treatments used as monotherapy and where appropriate in combination.

Role of the medicinal product in the therapeutic strategy

In view of:
- the low and non-clinically-relevant efficacy observed versus placebo,
- the absence of strong comparative data making it possible to specify the role of capsaicin compared with available alternatives that have Marketing Authorisation and are recommended in the treatment of painful diabetic neuropathy,
- the absence of a demonstrated reduction in pain treatments associated with the use of capsaicin,
- the frequency of painful reactions, in particular at the application site,
- the constraints of application (patient monitoring and precautions for use by the care staff),

QUTENZA has no role in the treatment of painful diabetic neuropathy.

* This summary does not cover this indication.

Clinical data

- In one study, the superiority of capsaicin compared with placebo was demonstrated on the change in percentage of the pain score from baseline to the period between weeks 2 and 8. Although the difference between the two treatments was statistically significant: -6.6% [95% CI: -12.3; -0.8], p=0.025, it was low and was not clinically relevant.
- The impact of repeated applications of capsaicin (30 min and 60 min for 1 year, i.e. 7 applications maximum, outside of the Marketing Authorisation [off-label]) in combination with a conventional treatment (CT) was assessed in a study with a low level of evidence due to its open-label nature.
- An indirect network comparison meta-analysis whose results were not very informative and of an exploratory nature did not find evidence of a statistically significant difference in efficacy between QUTENZA and oral treatments for painful diabetic neuropathy (pregabalin, gabapentin and duloxetine).
- The most common adverse effects were reactions at the injection site.

Special prescribing conditions

- Medicinal product reserved for hospital use.
- The Transparency Committee believes that QUTENZA should be prescribed after consultation with a pain specialist.

Benefit of the medicinal product

- The actual benefit* of QUTENZA in the treatment of peripheral diabetic neuropathic pain in adults, alone or in combination with other medicinal products for pain, is insufficient.
- Does not recommend 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 07 February 2018 (CT-15989) 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”.