BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

QUTENZA (capsaicin), local analgesic patch

No clinical benefit demonstrated in peripheral neuropathy pain

Main points

- QUTENZA is a transdermal system with Marketing Authorisation in the treatment of peripheral neuropathic pain in adults, either alone or in combination with other analgesics.
- Its efficacy is limited and its use is commonly associated with painful reactions at the application site.
- QUTENZA is a second-line and beyond treatment, in combination with other analgesics, in the management of local, evaluable and delimited peripheral neuropathic pain in nondiabetic adults.
- It should be prescribed after consultation with a pain specialist and its use must be re-evaluated regularly due to questions relative to its long-term use (maintenance of efficacy and absence of altered perception).

Indications

- Treatment of peripheral neuropathic pain in adults, either alone or in combination with other medicinal products for pain.
  This summary relates only to the indication “Treatment of peripheral neuropathic pain in nondiabetic adults, either alone or in combination with other medicinal products for pain”. The pharmaceutical company has not requested reimbursement in the adult diabetic population.

Therapeutic use

- In the management of neuropathic pain responding poorly or not at all to the usual analgesics (NSAIDs, paracetamol), the medicinal products used as first-line treatment are certain antidepressants (amitriptyline, imipramine, clomipramine, duloxetine) or certain antiepileptic agents (gabapentin, pregabalin). Their efficacy is moderate, limited by their safety profile and lacking predictive factors for response.
- The efficacy of strong opioids (oral morphine) and tramadol is established in peripheral neuropathic pain, particularly in diabetic neuropathy and neuropathy after shingles. Their prescription is recommended in chronic persistent neuropathic pain of high intensity after failure of first-line treatments used as monotherapy and, where appropriate, in combination.
- Lidocaine patches are a first-line treatment option in the treatment of pain after shingles when lesions are localised, particularly in elderly patients with allodynia and in whom systemic treatments are contraindicated or inadvisable.

Role of the medicinal product in the therapeutic strategy

QUTENZA is a second-line and beyond treatment, in combination with other analgesics, in the management of local, evaluable and delimited peripheral neuropathic pain in nondiabetic adults. Its use must be re-evaluated regularly.
Clinical data

- Clinical trials versus a placebo equivalent (0.04% capsaicin patch) demonstrated limited efficacy of QUTENZA in the treatment of peripheral neuropathic pain (PNP) in nondiabetic adults on the outcome measures (improvement in perceived pain or pain reduction of at least 30%) and etiology (pain after shingles or HIV-related pain).
- The new efficacy data available rely on open-label studies that tend to confirm this partial efficacy. These data do not resolve doubts relative to potential long-term alteration of perception and suggest that improvement in perceived pain does not increase with repeated application, justifying regular treatment re-evaluation. QUTENZA did not reduce the use of other analgesic treatments in 71% of cases.
- The safety profile and especially the high frequency of application site reactions was also confirmed by the new clinical data. In current practice, induced pain was reported in 14% of patients and led to premature removal of the patch in 4% of patients.

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 remains moderate only in the treatment of localised peripheral neuropathic pain in nondiabetic adults, in combination with other medicinal products for pain.
- The actual benefit* of QUTENZA is insufficient for reimbursement by National Health Insurance in the other clinical situations.
- QUTENZA does not provide clinical added value** (CAV V) in the management of localised peripheral neuropathic pain in nondiabetic adults.
- Recommends continued inclusion on the list of reimbursable products for hospital use.

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* 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”.

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