



TRANSPARENCY COMMITTEE SUMMARY

16 DECEMBER 2020

The legally binding text is the original French opinion version

netupitant + palonosetron
AKYNZEO 300 mg/0.5 mg hard capsules

Reevaluation

► Key points

Unfavourable opinion for reimbursement in adults for the prevention of acute and delayed nausea and vomiting associated with **moderately** emetogenic cancer chemotherapy.

As a reminder, this medicinal product already benefits from a favourable opinion for reimbursement in adults for the prevention of acute and delayed nausea and vomiting associated with **highly** emetogenic cancer chemotherapy

► What therapeutic improvement?

Not applicable.

► Role in the care pathway?

In adults, to prevent chemotherapy-induced nausea and vomiting, treatment must take into account the time to onset of the nausea and vomiting, as well as the emetogenic potential and administered doses of the chemotherapy.

The guidelines recommend one or more antiemetics, combined with corticosteroids. Several medicinal products can be used: as first-line treatment, serotonin 5-HT₃ receptor antagonists (anti-5HT₃ or “setrons”), corticosteroids (in particular dexamethasone) and type 1 neurokinin (NK₁) receptor antagonists (aprepitant, netupitant).

The addition of aprepitant to [setron + corticosteroid] dual therapy has demonstrated a reduction in the risk of vomiting after highly emetogenic chemotherapy (cisplatin-based for example) compared to the absence of aprepitant.

Role of the medicinal product in the prevention of acute and delayed nausea and vomiting associated with MODERATELY emetogenic cancer chemotherapy

Taking into account both the results and the limitations of the clinical study having evaluated the efficacy of AKYNZEO (netupitant/palonosetron) for the prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy (MEC), i.e.:

- the absence of demonstration of the non-inferiority of AKYNZEO versus the comparator combining setron + aprepitant (+ dexamethasone) in these patients, despite the study design having scheduled this analysis;
- the heterogeneity of the population included, with patients receiving both moderately and highly emetogenic chemotherapy, which, in particular, makes the choice of comparator questionable;
- the absence of comparison of AKYNZEO with a less aggressive antiemetic treatment recommended in the event of MEC (setron + corticosteroid, in particular).

The Committee deems that, on the basis of currently available data, the role of AKYNZEO (netupitant/palonosetron) cannot be specified for the prevention of acute and delayed nausea and vomiting associated with MODERATELY emetogenic cancer chemotherapy.

COMMITTEE'S CONCLUSIONS

Clinical Benefit in the re-evaluated indication

► Acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy (CINV) are incapacitating and cause a marked deterioration in quality of life. When inadequately controlled, CINV can compromise the continuation of cancer treatment and cause complications.

► AKYNZEO (netupitant + palonosetron) is a preventive treatment for chemotherapy-induced nausea and vomiting.

► Its efficacy/adverse effects ratio has still not been adequately established in the prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

► There are medicinal alternatives (see chapter 05: list of clinically relevant comparators).

► The role in the care pathway of AKYNZEO cannot be specified (see section 09: role in the care pathway).

Public health impact

Considering:

- the potential seriousness of chemotherapy-induced nausea and vomiting (CINV) and their prevalence,
- the need to improve the global management of cancer patients, in particular by preventing CINV, but the fact that this medical need is largely already met by the existing alternatives,
- the lack of elements supporting the absence of a deterioration in the care and life pathway in the absence of robust quality of life data,
- the lack of any demonstrated impact on the organisation of care (hospitalisation, AE, etc.),
- the lack of response to the identified need, already largely met by the available alternatives, in the absence of demonstration of its non-inferiority versus the study comparator and the absence of data versus the other existing alternatives,

AKYNZEO (netupitant + palonosetron) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of AKYNZEO remains insufficient to justify its public funding cover in view of the alternatives available for the prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

The Committee maintains its unfavourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the indication “prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy” and at the MA dosages.