Netupitant/palonosetron (Akynzeo®)

Summary of recommendations by *Zorginstituut Nederland* dated 31 October 2016

Zorginstituut Nederland has assessed the medicine netupitant/palonosetron (Akynzeo®), whereby they came to the following conclusion.
Based on the criteria of the Medicines Reimbursement System (GVS), netupitant/palonosetron is not interchangeable with any other product that is included in the GVS. Therefore it can be included in the GVS on List 1B for the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy, including highly emetogenic anthracycline and cyclophosphamide (A/C)-based chemotherapy. In cases of moderately emetogenic cancer chemotherapy there is no place for netupitant/palonosetron.

In a letter dated 7 March 2016 (CIBG-16-01790), the Minister of Health, Welfare and Sport asked *Zorginstituut Nederland* to perform a substantive assessment of whether the medicine netupitant/palonosetron (Akynzeo®) is interchangeable with a drug currently included in the GVS. With the advice of the Scientific Advisory Board (WAR), the Zorginstituut has now completed its assessment.

Registered indication

Netupitant/palonosetron is a combination product, comprised of a fixed combination of a 5-HT_3 receptor antagonist (palonosetron) and an NK1 receptor antagonist (netupitant). It is registered and indicated in adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic cancer chemotherapy.

It is available as a capsule containing 300 mg netupitant and 0.5 mg palonosetron (as hydrochloride). The recommended dose for adults is one capsule containing 300 mg netupitant and 0.5 mg palonosetron, taken about one hour prior to each cycle of chemotherapy.

Conclusion on interchangeability

Based on current criteria, netupitant/palonosetron (Akynzeo®) is not interchangeable with any other product in the GVS .
Based on the above, netupitant/palonosetron (Akynzeo®) cannot be placed on List 1A. It is necessary to determine whether it is eligible for inclusion on List 1B.

Therapeutic value

The final conclusion of Zorginstituut Nederland, advised by the WAR, is that netupitant/palonosetron has the same therapeutic value as the combination of the NK1 receptor antagonist aprepitant with a 5-HT_3 receptor antagonist for the prevention of nausea/vomiting associated with *highly emetogenic* chemotherapy (HEC), including highly emetogenic anthracycline and cyclophsophamide (A/C)-based chemotherapy.

No suitable studies with netupitant/palonosetron are available for the prevention of nausea and vomiting after *moderately emetogenic* chemotherapy. Furthermore, according to the most recent guidelines, there is no place for adding an NK-1 receptor antagonist to the standard treatment with a 5-HT_3 receptor antagonist in combination with dexamethasone in cases of moderately emetogenic chemotherapy.

Budget impact analysis

Inclusion on List 1B would involve total additional costs at the expense of the pharmacy budget of between €2,483 and €3,652. This is taking into account substitution with the cheapest 5-HT_3 receptor antagonist. This means it is highly likely that including netupitant/palonosetron in the GVS will lead to economies rather than additional costs. Exemption from a pharmacoeconomic analysis has been granted on the grounds of the estimated budget impact.

Zorginstituut Nederland's advice

Netupitant/palonosetron (Akynzeo®) has the same therapeutic value as the combination of the NK1 receptor antagonist aprepitant with a 5-HT_3 receptor antagonist for the prevention of nausea/vomiting associated with highly emetogenic chemotherapy (HEC), including highly emotogenic anthracycline and cyclophosphamide (A/C)-based chemotherapy. There is no place for netupitant/palonosetron (Akynzeo®) for the prevention of nausea and vomiting associated with moderately emetogenic chemotherapy.

Netupitant/palonosetron (Akynzeo®) is not interchangeable with any other product in the GVS. As inclusion in the GVS is more likely to lead to economies than to additional costs for the pharmacy budget, Zorginstituut Nederland advises the inclusion of netupitant/palonosetron (Akynzeo®) on List 1B.

For further information, please contact: JBoer@zinl.nl; warcg@zinl.nl

The original text of this excerpt from advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of Zorginstituut Nederland's advice.
Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.