HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
24 JUNE 2020

zanamivir
RELENZA 5 mg inhalation powder in a single-dose container

Discontinuation of reimbursement

Key points

Unfavourable opinion for maintenance of reimbursement in the treatment of influenza (for more details, see MA).

01 COMMITTEE'S CONCLUSIONS

01.1 Clinical benefit

1.1.1 Curative treatment for influenza

◗ Influenza is a highly contagious acute viral disease. Sometimes serious complications develop more readily in subjects already weakened by underlying diseases and/or over 65 years of age.

◗ RELENZA (zanamivir for oral inhalation) is a curative antiviral treatment in this indication.

◗ In the context of curative treatment and for the population eligible for treatment, the efficacy/adverse effects ratio of RELENZA has not been adequately established.

◗ There are therapeutic alternatives with an MA as a curative treatment for influenza: TAMIFLU (oseltamivir) and its generic EBILFUMIN and DECTOVA (zanamivir by injection).

◗ No reduction in mortality, hospitalisations or serious complications has been demonstrated with these treatments. Consequently, RELENZA (zanamivir for oral inhalation) no longer has a role in the treatment strategy, like the other abovementioned antivirals with an MA.

Public health impact

Considering:

- the frequency (2.5 million people affected each year) and potential severity of influenza, which can cause serious complications, particularly in individuals with specific risk factors (almost 2,000 serious cases admitted to intensive care units in the 2018-2019 season);
- the medical need to have access to an effective and well-tolerated curative antiviral treatment, particularly for at-risk populations in whom influenza is potentially life-threatening;
- data from clinical studies, which do not enable the impact of this medicinal product in terms of morbidity and mortality to be quantified, due to the absence of data on mortality and the weakness of the effect size on morbidity endpoints;
- the absence of any demonstrated impact on the organisation of care, in particular in terms of reduction of hospitalisations;

RELENZA (zanamivir for oral inhalation) is unlikely to have an impact on public health in the context of curative treatment of influenza infections.

Considering all these elements, the Committee deems that the clinical benefit of RELENZA is insufficient to justify its funding by the French national health insurance system in the context of the curative treatment of influenza in the event of a seasonal epidemic or influenza pandemic.

The Committee issues an unfavourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in "the treatment of both influenza A and B in adults and children (≥ 5 years) who present with symptoms typical of influenza when influenza is circulating in the community" and at the MA dosages.

1.1.2 Influenza prevention

◗ Influenza is a highly contagious acute viral disease. Sometimes serious complications develop more readily in subjects already weakened by underlying diseases and/or over 65 years of age.

◗ RELENZA (zanamivir for oral inhalation) is a preventive antiviral treatment in this indication.

◗ In the context of preventive treatment, the efficacy/adverse effects ratio of RELENZA has not been adequately established.

◗ There are therapeutic alternatives with an MA in the preventive treatment of influenza, in particular influenza vaccines, which are the cornerstone of influenza prevention, along with oseltamivir (TAMIFLU and its generic EBILFUMIN).

◗ In view of the available data, i.e.,:
- the demonstrated efficacy of vaccination combined with protective measures;
- the absence of a clearly demonstrated benefit of zanamivir in terms of reduction of the influenza attack rate in populations at risk of influenza complications;

RELENZA (zanamivir for oral inhalation) has no role in the influenza prevention strategy.

Public health impact

Considering:
- the frequency (2.5 million people affected each year) and potential severity of influenza, which can cause serious complications, particularly in individuals with specific risk factors (almost 2,000 serious cases admitted to intensive care units in the 2018-2019 season);
- the medical need to have an effective and well tolerated preventive antiviral treatment in addition to the available preventive measures (vaccination and protective measures);
- clinical data available in the general population only, in favour of a reduction in the influenza attack rate, without any clearly demonstrated benefit in terms of a reduction in mortality and associated serious complications, particularly in at-risk populations;
- the absence of any demonstrated impact on the organisation of care, in particular in terms of reduction of hospitalisations;

RELENZA (zanamivir for oral inhalation) is unlikely to have an impact on public health in the context of preventive treatment of influenza infections.

Considering all these elements, the Committee deems that the clinical benefit of RELENZA is insufficient to justify its funding by the French national health insurance system in the context of the preventive treatment of influenza in the event of a seasonal epidemic or influenza pandemic.

The Committee issues an unfavourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the prophylaxis of influenza in the indication and at the MA dosages.