INAHTA Brief

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Title FOSCAVIR – A Health Technology Assessment

Agency HAS, French National Authority for Health (Haute Autorité de santé)
2 avenue du Stade de France – F 93218 La Plaine Cedex, France
Tel: +33 (0)1 55 93 70 00 – Fax: +33 (0)1 55 93 74 35, contact.sem@has-sante.fr, www.has-sante.fr

Reference link to full report in French
https://www.has-sante.fr/jcms/p_3124477/fr/foscavir

Aim

Assessment of FOSCAVIR (foscarnet trisodium hexahydrate) with a view to funding by the French national health insurance system and of its clinical contribution compared to other strategies in a new indication: treatment of cytomegalovirus (CMV) infection in hematopoietic stem cell transplant (HSCT) recipients for whom the use of ganciclovir cannot be envisaged.

Conclusions of Transparency Committee

Substantial clinical benefit in the indication, considering:

- CMV infection is a serious infectious complication of HSCT and is one of the leading causes of morbidity and mortality in this situation.
- FOSCAVIR is part of a preventive treatment regimen.
- The efficacy/adverse effects ratio of FOSCAVIR is high, provided the special warnings and precautions for use are complied with, in particular adequate hydration to partially prevent the known risk of renal function impairment with foscarnet.
- It is a second-line treatment, when treatment with ganciclovir is impossible for reasons of resistance or tolerability.
- There are no second-line alternatives.
- Public health impact:
  Considering:
  - the severity of the disease and its incidence,
  - the inadequately met need in patients for whom the use of ganciclovir cannot be envisaged,
  - the response to the identified need (impact on the reduction of the occurrence of CMV disease and the associated morbidity/mortality),
  - the impact on the care pathway and/or life due to the possibility of its use if first-line options cannot be prescribed for reasons of resistance or tolerability,

FOSCAVIR is likely to have an impact on public health in the treatment of CMV infection in hematopoietic stem cell transplant (HSCT) recipients for whom the use of ganciclovir cannot be envisaged.

Clinical Added Value
Considering:

- the high efficacy of foscarnet with a high genetic resistance barrier and its activity in the event of resistance to ganciclovir or valganciclovir,
- the known and similar safety profile of foscarnet in the initially authorised indications,
- its already established use when the administration of ganciclovir is impossible, for reasons of resistance or tolerability (due, in particular, to its haematotoxicity),
- the absence of any alternative to foscarnet that has an MA and is well tolerated in the treatment of CMV infection, FOSCAVIR (foscarnet) provides an important clinical added value (CAV II) in the treatment of CMV infection in hematopoietic stem cell transplant (HSCT) recipients for whom the use of ganciclovir cannot be envisaged.

Recommendations

The Transparency Committee issued its approval for the funding of FOSCAVIR by the French national health insurance system (hospital use only) in the MA indication.

Methods

The assessment of FOSCAVIR was founded on evidence-based medicine with a critical analysis of the clinical data. The assessment of the efficacy and safety of FOSCAVIR is based on new clinical data.

Written by

HAS (Haute Autorité de santé), French National Authority for Health