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Title KEYTRUDA (cancer ORL) – 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/pprd_2982864/fr/keytruda

Aim

Assessment of KEYTRUDA (pembrolizumab) with a view to funding by the French national health insurance system and of its clinical contribution compared to other strategies in the indication combined with monotherapy or in combination with platinum salt and 5 fluorouracil (5 FU) chemotherapy, in the first-line treatment of adult patients with metastatic or non-resectable recurrent squamous cell carcinoma of the head and neck (SCCHN), the tumours of which are expressing PD-L1 with a CPS ≥ 1.

Conclusions of Transparency Committee

Clinical Benefit

- Upper aerodigestive tract carcinoma is a serious, life-threatening disease.
- This is a specific curative treatment for upper aerodigestive tract carcinoma.
- The efficacy/adverse effects ratio is high in metastatic or unresectable recurrent upper aerodigestive tract squamous cell carcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1.
- There are therapeutic alternatives.
- It is a first-line treatment.
- KEYTRUDA (pembrolizumab) s monotherapy is unlikely to have an additional impact on public health. Considering all of the above, the clinical benefit of KEYTRUDA (pembrolizumab) as monotherapy is substantial in the first-line treatment of metastatic or unresectable recurrent upper aerodigestive tract squamous cell carcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1.

Clinical Added Value - Upper aerodigestive tract squamous cell carcinoma as monotherapy
Considering:
- demonstration of the superiority of KEYTRUDA (pembrolizumab) as monotherapy compared to the EXTREME protocol, considered to be an acceptable comparator, in terms of overall survival (primary endpoint) with an absolute increase of 2 months in this population (HR = 0.78; 95%CI = [0.64; 0.96]; p=0.00855 < threshold of 0.0109)
- the favourable safety profile of this monotherapy compared to the EXTREME protocol,

and despite:
- the lack of demonstration of a benefit in terms of progression-free survival (primary endpoint),
- the absence of any data on quality-of-life with a demonstrative value,

KEYTRUDA as monotherapy provides a moderate clinical added value (CAV III) compared to the EXTREME protocol in patients whose tumours express PD-L1 with a CPS ≥ 1.

Clinical Added Value - Upper aerodigestive tract squamous cell carcinoma in combination with chemotherapy
Considering:
- demonstration of the superiority of KEYTRUDA (pembrolizumab) + platinum and 5-FU chemotherapy compared to the EXTREME protocol, considered to be an acceptable comparator, in terms of overall survival (primary endpoint) with an absolute increase of 3.2 months in this population (HR = 0.65; 95%CI = [0.53; 0.80]; p=0.00002 < threshold of 0.0026)
- increased toxicity in the context of its combination with chemotherapy, in particular the incidence of serious AEs (59.8% versus 49.1%)
- the lack of demonstration of a benefit in terms of progression-free survival (primary endpoint)
- the absence of any data on quality-of-life with a demonstrative value,

KEYTRUDA in combination with platinum and 5-FU chemotherapy provides low Clinical Added Value (CAV IV) compared to the EXTREME protocol in patients whose tumours express PD-L1 with a CPS ≥ 1.

Recommendations

The Transparency Committee issued its approval for the funding of KEYTRUDA (pembrolizumab) by the French national health insurance system (hospital only) in the indication as monotherapy or in combination with platinum salt and 5 fluorouracil (5 FU) chemotherapy, in the first-line treatment of adult patients with metastatic or non-resectable recurrent squamous cell carcinoma of the head and neck (SCCHN), the tumours of which are expressing PD-L1 with a CPS ≥ 1.

Methods

The assessment of KEYTRUDA (pembrolizumab) was founded on evidence-based medicine with a critical analysis of the clinical data.

Written by

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