INAHTA Brief

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Title DARZALEX – A Health Technology Assessment

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Reference link to full report in French
https://www.has-sante.fr/jcms/pprd_2982754/fr/darzalex

Aim

Assessment of DARZALEX (daratumumab) with a view to funding by the French national health insurance system and of its clinical contribution compared to other strategies, with a view to setting of its price by the French Healthcare Products Pricing Committee (CEPS), as part of re-assessment of its clinical benefit in the indication "in combination with bortezomib, melphalan and prednisone in the treatment of adult patients with newly diagnosed multiple myeloma, not eligible for stem cell autograft".

Conclusions of Transparency Committee

Substantial clinical benefit in the indication above, considering:

- Multiple myeloma is a serious, life-threatening blood disease.
- DARZALEX (daratumumab) is a specific curative treatment for multiple myeloma.
- The efficacy/adverse effects ratio of DARZALEX (daratumumab) in combination with bortezomib, melphalan and prednisone is high.
- There are alternative medicinal products.
- This is a first-line treatment for adult patients not eligible for stem cell autograft, administered until progression of the disease, in combination with 9 cycles of the VMP (bortezomib, melphalan and prednisone) protocol
- Public health benefit:

DARZALEX (daratumumab) is unlikely to have an additional impact on public health.

Moderate Clinical Added Value (CAV III) in the indication above, taking into consideration:
- demonstration of the superiority of adding DARZALEX (daratumumab) to bortezomib, melphalan and prednisone (D-VMP protocol) compared to the VMP protocol, in terms of overall survival (40% reduction in the risk of death, HR = 0.60 [95%CI: 0.46 – 0.80]) following a median follow-up of 40 months,
- and confirmation of an increase in progression-free survival (median increase of 17 months),
and despite:
- the lack of demonstrated impact on quality-of-life,
- and the higher frequency of serious adverse events with the D-VMP protocol compared to the VMP protocol (48% versus 33%), in particular more cases of serious pneumonia (12% versus 3%).

Recommendations

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

Methods

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

Written by

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