HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
6 OCTOBER 2021

The legally binding text is the original French opinion version

abatacept
ORENCIA 125 mg pre-filled pen and syringe
ORENCIA 250 mg powder for concentrate for solution for infusion

Re-evaluation

Key points

Favourable opinion for maintenance of reimbursement, in combination with methotrexate, in the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a tumour necrosis factor (TNF)-alpha inhibitor.

Special recommendations

The Committee reiterates that subcutaneous treatment must be initiated by specialists. ORENCIA subcutaneous (SC) may be initiated with or without an intravenous (IV) loading dose. Given the rare but serious identified risk of systemic reactions following injection, including anaphylactic reactions observed with subcutaneous abatacept but also with other biologic disease-modifying drugs, the Transparency Committee considers that the first subcutaneous injection of this drug should be given in an appropriate care structure.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

- Rheumatoid arthritis is a serious, chronic debilitating condition.
- The medicinal product ORENCIA (abatacept) is a symptomatic medicinal product.
- The efficacy/adverse effects ratio remains high.
- There are therapeutic alternatives (see section 04 of this opinion).
- ORENCIA (abatacept) can be used in the treatment of rheumatoid arthritis at the same stage in the strategy as TNF antagonists, i.e. in patients in whom conventional DMARD therapy, including methotrexate, has failed, or following the failure of at least one TNF antagonist (see section 07 of this opinion).

Public health impact:

ORENCIA (abatacept) is unlikely to have an additional impact on public health.

The Committee deems that the clinical benefit of ORENCIA (abatacept) remains substantial, in combination with methotrexate, in the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a tumour necrosis factor (TNF)-alpha inhibitor.

The Committee issues a favourable 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 marketing authorisation indication and at the MA dosages.

- **Recommended reimbursement rate: 65%**

Clinical Added Value

The Committee considers that the new data available is not of a nature to modify the assessment of the clinical added value formulated in its previous opinions of 18/07/2007, 14/03/2012, 04/12/2013 and 22/06/2016.