OPINION ON MEDICINAL PRODUCTS

tofacitinib

XELJANZ 5 and 11 mg,

film-coated tablets and sustained-release tablets

New indication

Adopted by the Transparency Committee on 14 December 2022

SUMMARY

The legally binding text is the original French opinion version

Key points

Approval of reimbursement for the “Treatment of adult active ankylosing spondylarthritis patients responding poorly to conventional treatment”

Therapeutic improvement?

No therapeutic improvement, based on the data available.

Transparency Committee's conclusion

Clinical Benefit

- Ankylosing spondylarthritis is a chronic disease which, in its severe form with poor response or intolerance to NSAIDs, is painful, and affects spinal mobility and functional capacities.
- This medicinal product is a symptomatic basic treatment.
- The efficacy/adverse effect ratio is low considering the effect size versus placebo, the lack of data on structural efficacy, limited data as a third-line treatment and the concerning safety profile of the JAK inhibitor class.
- Availability of alternatives: Therapeutic alternatives are available for this indication represented particularly by TNF inhibitors, IL 17 inhibitors and another JAK inhibitor. (see CRC section).
- This medicinal product is a third-line or subsequent treatment after failure to respond to TNF inhibitors and/or IL17A inhibitors. Note that the Committee recommends that, in the event of failure to respond to a TNF inhibitor or if a change of therapeutic target is envisaged, preference must be given to IL17 inhibitors.

Public health benefit

Considering:

- the severity of the disease;
- the medical need partially met by TNF inhibitors, IL17A inhibitors and upadacitinib;
- the partial response to the identified need considering:
  - the lack of evidence of an additional impact on morbidity-mortality and quality of life, in the absence of robust comparative data versus the clinically relevant comparators (TNF inhibitor or interleukin 17 A inhibitor) recommended by the EMA, while a direct comparison was feasible;
  - therapeutic failure, poor response, contraindications and intolerance to TNF inhibitors;
  - the lack of evidence of an impact on delivery of care and the care pathway,

XELJANZ (tofacitinib) is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of XELJANZ (tofacitinib) is low in the extension of the marketing authorisation indication.

The Committee approves inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary products approved for community use for the extension of indication and at the dosages of the marketing authorisation.

Recommended reimbursement rate: 15%

Clinical Added Value

Considering:

- the evidence of the clinical benefit versus placebo in terms of ASAS 20 and 40 response percentages, disease activity, functional capacities and quality of life on 270 patients at week 16 and the suggested maintained effect at week 48 on the ASAS 20 outcome measure;
- the lack of data on structural efficacy, clinically relevant outcome measure for this indication;
- the lack of comparative data versus TNF inhibitors or IL17 inhibitors while comparison was feasible,
- the lack of robust data on patients failing to respond to biological treatment (i.e. as a third and subsequent line),
- and concerns in terms of long-term safety, particularly in relation to infection risks and the potential cardiovascular and carcinogenic risks,

the Committee deems that XELJANZ (tofacitinib) provides no clinical added value (CAV V) in the current therapeutic strategy.