SUMMARY

risankizumab

SKYRIZI 360 mg and 600 mg,

360 mg solution for injection in cartridge, 600 mg concentrate for solution for infusion

New indication(s)

Original French opinion adopted by the Transparency Committee on 5 April 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion on the inclusion of SKYRIZI (risankizumab) 360 mg, solution for injection in cartridge and of SKYRIZI 600 mg, concentrate for solution for infusion in the treatment of moderately to severely active Crohn's Disease in adult patients in whom a conventional treatment (corticosteroids or immunosuppressants) and at least one anti-TNFα agent have failed (insufficient response, loss of response or intolerance) or who have a medical contraindication to these treatments.

Unfavourable opinion on the inclusion of SKYRIZI (risankizumab) 360 mg, solution for injection in cartridge and of SKYRIZI 600 mg, concentrate for solution for infusion in the treatment of moderately to severely active Crohn's Disease in adult patients in whom a conventional treatment has failed and who are anti-TNF naive.

Role in the care pathway?

➔ **Within the area of reimbursement:**

In the treatment of moderately to severely active Crohn's Disease in adult patients in whom a conventional treatment (corticosteroids or immunosuppressants) and at least one anti-TNFα agent have failed (insufficient response, loss of response or intolerance) or who present with a medical contraindication to these treatments: the role of SKYRIZI in the management of Crohn's Disease is, like that of vedolizumab and ustekinumab, a third-line treatment, that is after failure of a

conventional treatment including an immunosuppressant (including azathioprine and 6-mercaptopurine) or a corticosteroid and at least one anti-TNF (adalimumab, infliximab).

➔ **Within the area included in the MA but not selected for reimbursement:**

After failure of a conventional treatment including an immunosuppressant (including azathioprine and 6-mercaptopurine) or a corticosteroid but in anti-TNF naive patients: SKYRIZI (risankizumab) does not have an established role.

Transparency Committee's Conclusions

Clinical Benefit

- ➔ Crohn's Disease is a chronic inflammatory bowel disease (IBD). It progresses in flares interspersed with remissions. It is a disabling pathology that causes a marked deterioration in quality of life.
- ➔ SKYRIZI is a symptomatic treatment.
- ➔ The efficacy/adverse effect ratio of risankizumab in the third-line treatment of moderately to severely active Crohn's Disease is significant.
- ➔ STELARA is a third-line treatment that is after failure of a conventional treatment including an immunosuppressant (including azathioprine and 6-mercaptopurine) or a corticosteroid and at least one anti-TNF (adalimumab, infliximab) (see 5.1).

➔ **Public health benefit**

In view of:

- the gravity of Crohn's Disease: a serious chronic and disabling disease responsible for a significant deterioration in quality of life with high morbidity due to the frequency of flares, its complications and recourse to surgery, the low prevalence of moderately to severely active forms with failure of conventional treatments and anti-TNFα agents,
- the partially met medical need, particularly in third-line treatment,
- an additional impact on morbidity not demonstrated due to:
  - the absence of robust data on colectomy and remission without corticosteroids, fistulae, and on quality of life at 52 weeks,
  - the absence of a robust comparison with other second-line and third-line treatments available,
- the absence of additional expected impact in terms of organisation of care, the patient's care pathway and life course particularly in maintenance therapy,

SKYRIZI (risankizumab) 360 mg and 600 mg is not liable to have an additional impact on public health.

In view of all of these elements, the Committee considers that the clinical benefit provided by SKYRIZI (risankizumab) 360 mg, solution for injection in cartridge and by SKYRIZI 600 mg, concentrate for solution for infusion is significant solely in the treatment of moderately to severely active Crohn's Disease in adult patients in whom a conventional treatment (corticosteroids or immunosuppressants) and at least one anti-TNFα agent has failed (insufficient

response, loss of response or intolerance) or who have a medical contraindication to these treatments.

The Committee gives a favourable opinion on the inclusion of SKYRIZI (risankizumab) 360 mg, solution for injection in cartridge and of SKYRIZI 600 mg, concentrate for solution for infusion on the list of medicinal products reimbursable to persons insured under social insurance schemes and on the list of medicinal products approved for the use of communities solely in these patients and at the MA doses.

➔ **Recommended reimbursement rate: 65 %**

The Committee gives an unfavourable opinion on the inclusion of SKYRIZI (risankizumab) 360 mg, solution for injection in cartridge and of SKYRIZI 600 mg, concentrate for solution for infusion on the list of medicinal products reimbursable to persons insured under social insurance schemes and on the list of medicinal products approved for the use of communities in the treatment of moderately to severely active Crohn's Disease in adult patients in whom a conventional treatment has failed and who are anti-TNF naive.

Clinical Added Value

In patients in whom conventional treatments (corticosteroids or immunosuppressants) and at least one anti-TNFα agent have failed in view of:

- the methodological quality of the demonstration of efficacy of SKYRIZI (risankizumab) in three controlled randomised studies versus placebo conducted in patients in most of whom at least one anti-TNF agent had failed, and who had above all a moderate form of Crohn's Disease (CD),
- the size of the clinically relevant effect compared to placebo on clinical remission and the endoscopic response at W12 and W52 and a proven effect on fatigue at W12,
- the reduced robustness of this demonstration for maintenance therapy,
- the absence of additional established impact with risankizumab on the complications (fistulae, stenoses), the extraintestinal manifestations of Crohn's Disease and recourse to surgery,
- the known tolerance profile of SKYRIZI (risankizumab) in Crohn's Disease,
- the data on efficacy and tolerance currently available to locate it relative to clinically relevant comparators, (STELARA and ENTYVIO), and while waiting for the full results of the direct comparison of ustekinumab vs risankizumab, particularly in maintenance therapy,

the Committee considers that SKYRIZI 360 (SC route) and 600 mg (IV infusion) (risankizumab), provides no clinical added value (CAV V) in the current therapeutic strategy which includes relevant comparators (see 5.2).

The benefit relative to risankizumab (SKYRIZI) in comparison to ustekinumab (STELARA) in patients in whom anti-TNF treatment has failed may be reassessed on the basis of the expected and definitive results of the SEQUENCE study.