SUMMARY

risankizumab

SKYRIZI 360 mg and 600 mg

solution for injection in cartridge (360 mg strength) and concentrate for solution for infusion (600 mg strength)

Reassessment

Original French opinion adopted by the Transparency Committee on 28 February 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement in the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy (corticosteroids or immunosuppressants) and at least one anti-TNFα agent, or who have a medical contraindication to these treatments.

Unfavourable opinion for reimbursement in the treatment of adult patients with moderately to severely active Crohn's disease with previous failure to conventional therapy and with no prior anti-TNFα agent therapy.

Transparency Committee's conclusions

Clinical Benefit

- Crohn's disease is a chronic inflammatory bowel disease (CIBD). It progresses in flare-ups interspersed by periods of remission. It is a disabling disease that causes a marked deterioration in quality of life.
- This is a symptomatic/preventive medicinal product.
- The efficacy/adverse effect ratio of risankizumab in the third-line treatment of adult patients with moderately to severely active Crohn's disease is high. It is still to be established in patients with no prior anti-TNFα agent therapy,
- This is a third-line treatment in view of the therapies available (see 5.1).

➔ Public health benefit

Considering:

- the seriousness of Crohn's disease: a serious and disabling chronic disease that significantly impairs quality of life and with high morbidity due to the frequency of flare-ups, its complications and recourse to surgery, the low prevalence of moderately to severely active forms with previous failure to conventional therapies and anti-TNFα agent therapy,
- the partially met medical need, particularly in third-line treatment,
- the partial response to this need, with:
  - the absence of clinical data to position risankizumab compared to TNF inhibitors in patients with no previous anti-TNFα agent therapy (second-line)
  - an established additional impact on control of Crohn's disease compared to one of the clinically relevant comparators, ustekinumab (STELARA) after 52 weeks of treatment (third line),
  - no evidence of an additional impact on morbidity due to the lack of robust data on colectomy and corticosteroid-free remission, fistulas, and on quality of life at 52 weeks,
- the absence of an expected additional impact in terms of organisation of care and the patient's care and life pathway during maintenance therapy,

SKYRIZI (risankizumab) 360 mg and 600 mg is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of SKYRIZI (risankizumab) 360 mg solution for injection in cartridge and SKYRIZI 600 mg concentrate for solution for infusion remains substantial in the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy (corticosteroids or immunosuppressants) and at least one anti-TNFα agent, or who have a medical contraindication to these treatments.

The Committee issues a favourable opinion for maintenance of inclusion of SKYRIZI (risankizumab) 360 mg solution for injection in cartridge and SKYRIZI 600 mg concentrate for solution for infusion in both the list of covered drugs for inpatients and the list of covered drugs for outpatients approved for use solely in these patients and at the MA dosages.

➔ Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%

The Committee issues an unfavourable opinion for inclusion of SKYRIZI (risankizumab) 360 mg solution for injection in cartridge and SKYRIZI 600 mg concentrate for solution for infusion in both the list of covered drugs for inpatients and the list of covered drugs for outpatients approved for use in the treatment of adult patients with moderately to severely active Crohn's disease with previous failure to conventional therapy and with no prior anti-TNFα agent therapy.

Clinical Added Value

Considering:

- the methodological quality of the evidence of the efficacy of SKYRIZI (risankizumab) in three randomised, placebo-controlled studies, conducted in patients who mostly had previous failure to at least one TNF inhibitor and predominantly had a moderate form of Crohn's disease (CD);
- the clinically relevant effect size versus placebo on clinical remission and endoscopic response at W12 and W52, and a demonstrated effect on fatigue at W12;
- the lower robustness of this evidence for the maintenance treatment;
- the results of the direct comparison between ustekinumab and risankizumab in a study of good methodological quality (randomised although single-blind, versus ustekinumab, a clinically relevant comparator and prescribed at an optimised dosage) having demonstrated the superiority of risankizumab, with an effect size deemed to be moderate;
- the absence of an established additional impact with risankizumab on complications (fistula, stenosis), extraintestinal manifestations of Crohn's disease and recourse to surgery;
- the known safety profile of SKYRIZI (risankizumab) in Crohn's disease;

the Committee deems that SKYRIZI 360 mg and 600 mg solution for injection in cartridge (360 mg strength) and concentrate for solution for infusion (600 mg strength) provide a minor clinical added value (**CAV IV**) **compared to STELARA (ustekinumab) at an optimised dosage (SC injection every 8 weeks) in the third-line treatment of adult patients with moderately to severely active Crohn's disease, i.e. after previous failure to conventional therapy including an immunosuppressant (such as azathioprine or 6-mercaptopurine) or a corticosteroid and at least one TNF inhibitor (adalimumab, infliximab).**