HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
08 JANUARY 2020

dasatinib
SPRYCEL 20 mg, 50 mg, 70 mg, 100 mg, 140 mg film-coated tablets and 10 mg/mL powder for oral suspension

New indication

Key points

Favourable opinion for reimbursement in paediatric patients with newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL)[1].

What therapeutic improvement?

No clinical added value.

Role in the care pathway?

The current care pathway in the first-line treatment of acute lymphoblastic leukaemia in paediatric patients is based on the combination of imatinib (GLIVEC) with multi-agent chemotherapy following an induction, consolidation, maintenance regimen. Depending on the situations (in particular Ph+ ALL at high risk of relapse) and in the event of a compatible HLA donor, allogeneic hematopoietic stem cell transplantation (HSCT) may be envisaged after first remission is obtained.

[1] See complete indications on page 3 of the opinion

Role of the medicinal product in the care pathway

SPRYCEL (dasatinib), in the form of film-coated tablets or powder for oral suspension, is an alternative to GLIVEC (imatinib), as a film-coated tablet, in the treatment of paediatric patients with newly diagnosed Ph+ ALL in combination with chemotherapy. The Committee highlights the benefit of having access to a powder for oral suspension form and reiterates that the two oral forms (tablets and powder) are not bioequivalent. The recommendations relative to dosage (see SPC) must be followed when switching from one form to the other.

COMMITTEE'S CONCLUSIONS

Clinical Benefit

◗ Childhood Philadelphia chromosome positive (Ph+) B-cell acute lymphoblastic leukaemia (Ph+ ALL) is a rare and serious malignant blood disease that is life-threatening.
◗ SPRYCEL (dasatinib) is a specific curative treatment for Ph+ ALL.
◗ The efficacy/adverse effects ratio is high.
◗ There is a therapeutic alternative in newly diagnosed patients: GLIVEC (imatinib).
◗ SPRYCEL (dasatinib), in the form of film-coated tablets or powder for oral suspension, is an alternative to GLIVEC in the treatment of paediatric patients with newly diagnosed Ph+ ALL in combination with chemotherapy.

Public health impact
Considering:
- the seriousness of Ph+ ALL,
- its low incidence in children,
- the medical need covered in first-line treatment by GLIVEC (imatinib),
- the lack of additional response to the identified need in the absence of any demonstrated additional impact on morbidity and mortality (only superiority *versus* chemotherapy and non-inferiority *versus* imatinib demonstrated in a study with methodological limitations),
- the lack of demonstrated impact on quality of life or the organisation of care in the absence of data,

SPRYCEL is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of SPRYCEL is substantial in the indication for paediatric patients with newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) in combination with chemotherapy.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the indication for paediatric patients with newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) in combination with chemotherapy and at the MA dosages.

◗ **Recommended reimbursement rate: 100%**

Clinical Added Value

Considering:
- **the available efficacy data derived from a phase 2 single-arm comparative study *versus* a historic cohort having demonstrated the non-inferiority of dasatinib *versus* imatinib, in combination with chemotherapy, and the methodological reservations raised;**
- **the absence of a direct comparison *versus* imatinib, despite this being feasible;**
- **the medical need covered by imatinib in combination with chemotherapy in paediatric patients with newly diagnosed Ph+ ALL;**

the Transparency Committee considers that SPRYCEL (dasatinib) in combination with chemotherapy provides no clinical added value (CAV V) in the care pathway for the treatment of paediatric patients with newly diagnosed Ph+ ALL in combination with chemotherapy.