SUMMARY

Lucilia sericata

SERILIA 50, 100, 200 and 300,

larval therapy

Reassessment

Adopted by the Transparency Committee on 10 May 2023

The legally binding text is the original French opinion version

Key points

Unfavourable opinion for reimbursement in the “debridement of chronic or difficult-to-heal wounds when instrumental/surgical treatment is not desired”.

Transparency Committee's conclusions

Clinical Benefit

- The population concerned by chronic wounds is generally elderly, with comorbidity factors (obesity, diabetes mellitus, venous or arterial insufficiency, etc.). Wounds with necrotic tissue and a high slough content heal badly and are prone to secondary infection, which may require recourse to surgical interventions or even amputations. They can be life-threatening.
- SERILIA (*Lucilia sericata)* larval therapy medicinal products are curative products.
- Considering the results of the comparative randomised VenUS II study and new data from the literature that do not enable any solid conclusions to be drawn in the absence of a robust methodology, and in view of the absence of data in the subpopulation concerned by the pharmaceutical company's application, the efficacy/adverse effects ratio of SERILIA larval therapy is not established in the debridement of chronic necrotic or sloughy wounds, following the failure of debridement after dressing treatment and when instrumental and/or surgical treatment is not possible, as in the other situations of the MA indication.
- In view of the new clinical data available, SERILIA (*Lucilia sericata*) larval therapy medicinal products have no role in the care pathway:
  - after the failure of dressing treatment and when instrumental and/or surgical treatment is not possible (claimed indication).
  - in the other situations of the MA indication.

Public health benefit

Considering:

- the seriousness of chronic wounds due to the risk of complications,
- the unmet medical need in situations of failure of debridement after dressing treatment and when instrumental and surgical treatment is not possible.
- the lack of response to the identified unmet need, with the absence of any demonstrated additional impact of SERILIA larval therapy on morbidity and mortality and quality of life,

SERILIA larval therapy is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of SERILIA (*Lucilia sericata*) larval therapy is insufficient in the MA indication (including the claimed indication "the debridement of chronic necrotic or sloughy wounds, following the failure of debridement after dressing treatment and when instrumental and/or surgical treatment is not possible") to justify public funding cover.

The Committee issues an unfavourable opinion for inclusion of SERILIA (*Lucilia sericata*) larval therapy in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indication (including the claimed indication "the debridement of chronic necrotic or sloughy wounds, following the failure of debridement after dressing treatment and when instrumental and/or surgical treatment is not possible") and at the MA dosages.