Wounds
Sector: Hospital

HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
21 APRIL 2021

Lucilia sericata (green bottle fly)
SERILIA 50, larval therapy
SERILIA 100, larval therapy
SERILIA 200, larval therapy
SERILIA 300, larval therapy

First assessment

Key points

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

◗ Role in the care pathway?

When instrumental or surgical methods are not used, the most appropriate dressings for desloughing are alginate-based ones in the event of highly exuding wounds, or hydrogel-based ones. Hydrocolloids can be used irrespective of healing phase.

Role of the medicinal product in the care pathway

Considering:

- firstly, the medical need to achieve debridement of chronic or difficult-to-heal wounds if instrumental or surgical techniques are not used, currently met by the available dressings, in particular hydrogels, and in the event of highly exuding wounds, alginates, which are specifically indicated in the desloughing phase, and hydrocolloids, which can be used for every healing phase, including desloughing,
- secondly, the results of the VenUS II study not having demonstrated the superiority of SERILIA larval therapy compared to a hydrogel-based dressing (clinically relevant comparator) on the primary endpoint (time to complete healing),

the Transparency Committee considers that, on the basis of currently available data, the benefit of SERILIA larval therapy medicinal products has not been demonstrated in the debridement of chronic or difficult-to-heal wounds when instrumental/surgical treatment is not desired. Consequently, these medicinal products have no role in the care pathway.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

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.

◗ In view of the results of the VenUS II study, which were not statistically significant for the primary endpoint (time to complete healing), their efficacy/adverse effects ratio has not been established compared to hydrogel-based dressings (a clinically relevant comparator) in the debridement of chronic or difficult-to-heal wounds when instrumental/surgical treatment is not desired.

◗ There are non-medicinal alternatives: when an instrumental or surgical method is not used, the debridement of chronic or difficult-to-heal wounds can use autolytic desloughing methods, including hydrogel, hydrocolloid, hydrofibre or absorbent dressings. The most appropriate dressings for desloughing are alginate-based ones in the event of highly exuding wounds, and hydrogel-based ones.

◗ In view of the clinical data available, SERILIA medicinal products have no role in the care pathway when instrumental/surgical treatment is not desired (see section 08).

◗ **Public health impact**

Considering:
- the seriousness of chronic wounds due to the risk of complications,
- the already met medical need,
- the lack of response to the already met need due to non-demonstration of an additional impact of SERILIA (*Lucilia sericata)* larval therapy on morbidity and mortality and on quality of life compared to the hydrogel-based dressing,

SERILIA (*Lucilia sericata)* 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 to justify public funding cover in the MA indication in view of the available alternatives.

The Committee issues an unfavourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and dosages.