HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
11 MARCH 2020

pancreatin
CREON (PANCREATIN) 35,000 U gastro-resistant capsules

First assessment

Key points

Favourable opinion for reimbursement in pancreatic enzyme replacement therapy in exocrine pancreatic insufficiency associated with cystic fibrosis and other diseases (for example, chronic pancreatitis, pancreatectomy or pancreatic cancer).

What therapeutic improvement?

No clinical added value compared to other CREON (pancreatin) proprietary medicinal products in pancreatic enzyme replacement therapy in exocrine pancreatic insufficiency (EPI) associated with cystic fibrosis and other diseases (for example, chronic pancreatitis, pancreatectomy) and in the treatment of EPI associated with unresectable pancreatic cancer.

Role in the care pathway?

Overall strategy:

Following a diagnosis of exocrine pancreatic insufficiency (EPI) confirmed by assay of faecal elastase and as long as meals and snacks contain fats, it is recommended that enteric-coated pancreatic enzymes, represented by the proprietary medicinal products CREON (pancreatin) and EUROBIOL (porcine pancreas powder) be prescribed as first-line treatment. It should be noted that the efficacy of CREON (pancreatin) is related to its intrinsic pharmacological properties, irrespective of dosage.

Role of CREON 35,000 U (pancreatin) in the care pathway:

CREON 35,000 U (pancreatin) is a first-line treatment for exocrine pancreatic insufficiency (EPI) associated with cystic fibrosis and other diseases (for example, chronic pancreatitis, pancreatectomy or pancreatic cancer).

Special recommendations

The use of pancreatic extracts outside the indication “exocrine pancreatic insufficiency”, for example in the treatment of dyspepsia, is not justified and constitutes misuse.

COMMITTEE'S CONCLUSIONS

Clinical Benefit

◗ Exocrine pancreatic insufficiency is a serious condition resulting in potentially life-threatening undernutrition.
◗ This proprietary medicinal product is a replacement therapy.
◗ In the same way as the other CREON (pancreatin) dosages, the efficacy/adverse effects ratio of CREON 35,000 U (pancreatin) is high.
◗ There are therapeutic alternatives.
◗ CREON 35,000 U (pancreatin) is a first-line treatment for exocrine pancreatic insufficiency (EPI) associated with cystic fibrosis and other diseases (for example, chronic pancreatitis, pancreatectomy or pancreatic cancer).

◗ Public health impact:
Considering:
- the seriousness of the disease,
- its prevalence/incidence,
- the medical need, which is considered to be met in pancreatic enzyme replacement therapy in EPI associated with cystic fibrosis and other diseases (for example, chronic pancreatitis, pancreatectomy or pancreatic cancer),
- the lack of any additional response provided by CREON 35,000 U (pancreatin) in terms of morbidity and mortality,
- the absence of robust data in terms of the potential impact of CREON 35,000 U (pancreatin) on quality of life,
- the absence of data enabling assessment of a potential impact of CREON 35,000 U (pancreatin) on the organisation of care,

CREON 35,000 U (pancreatin) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of CREON 35,000 U (pancreatin) is substantial in the MA indication.

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 marketing authorisation indication(s) and dosages.

Clinical Added Value

Treatment of EPI associated with cystic fibrosis and chronic pancreatitis and following pancreatectomy

In pancreatic enzyme replacement therapy in exocrine pancreatic insufficiency associated with cystic fibrosis and other diseases (for example, chronic pancreatitis, pancreatectomy), the Committee considers that CREON 35,000 U (pancreatin) is a line extension that provides no clinical added value (CAV V) compared to the proprietary medicinal products already listed.

Treatment of EPI associated with unresectable pancreatic cancer

In pancreatic enzyme replacement therapy in exocrine pancreatic insufficiency associated with unresectable pancreatic cancer, considering:
- **the low level of evidence of the data available, not enabling evaluation of the new dosage of CREON 35,000 U (pancreatin) in the treatment of EPI associated with unresectable pancreatic cancer;**

- **the already defined recommendations specifying the central role of supportive care, including the treatment of EPI by enzyme replacement therapy, in unresectable pancreatic cancer;**
- **its safety profile that appears to be favourable;**

the Committee considers that CREON 35,000 U (pancreatin) provides no clinical added value (CAV V) in the treatment of EPI associated with unresectable pancreatic cancer.