



The Board of Directors has given the go-ahead for reimbursing a new medicine, seven extensions of therapeutic indications and three generic equivalents

The medicines to be reimbursed include new indications for the treatment of metastatic prostate cancer, newly diagnosed multiple myeloma and hepatitis delta virus (HDV) infection, as well as a medicine for pre-exposure prophylaxis against HIV-1 infection

Apretude (cabotegravir LA) will be reimbursed by the National Health Service. This medicine is indicated for pre-exposure prophylaxis to reduce the risk of sexually transmitted HIV-1 infection in adults and adolescents aged 16 years and over, in combination with safe sexual practices. The medicine will be reimbursed under class H/RNRL (on prescription from hospitals or infectious disease specialists), with prescriptions to be issued via a paper AIFA hospital prescription form completed by the doctor. The form sets out in detail the clinical conditions, reimbursement and patient eligibility criteria, administration methods, and parameters for clinical assessment and monitoring.

Administration consists of an initial injection followed by a second injection one month later. Single maintenance injections are scheduled every two months.

Apretude represents an additional therapeutic option for pre-exposure prophylaxis compared to the already reimbursed combination of emtricitabine/tenofovir disoproxil, oral tablets to be taken daily.

EXTENSION OF THERAPEUTIC EXTENSION

The extensions of therapeutic indications for medicines already reimbursed for other indications concern the following medicines:

- **Darzalex** (daratumumab), 2 new indications for the treatment of multiple myeloma in combination with other medicines.
- **Fasenra** (benralizumab), for the treatment of eosinophilic granulomatosis with polyangiitis.
- **Hepcludex** (bulevirtide), for the treatment of chronic hepatitis delta virus (HDV) infection in paediatric patients.
- **Nubeqa** (darolutamide), for the treatment of hormone-sensitive metastatic prostate cancer.
- **Takhzyro** (lanadelumab), for the routine prevention of recurrent attacks of hereditary angioedema (HAE).
- **Clopidogrel and Viatris acetylsalicylic acid** (clopidogrel and acetylsalicylic acid), for acute coronary syndrome.

GENERIC MEDICINES

The three new generic equivalents and the new therapeutic indication that will be reimbursed by the NHS are:

- **Illuccix** (gozetotide), a medicinal product for diagnostic use.
- **Perampanel Teva** (perampanel), indicated for the treatment of epileptic seizures.
- **Teduglutide Viatris** (teduglutide), indicated for patients with short bowel syndrome.

With regard to the new monoclonal antibodies authorised for the treatment of the early stages of Alzheimer's disease, the Board of Directors, given the social significance of the issue, has decided to call for patient associations and relevant scientific societies to examine in greater depth the issues relating to eligibility criteria and the organisational aspects of these treatments.