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Duchenne and multiple myeloma: the NHS reimburses two innovative therapies

AIFA Board of Directors Approves 6 new medicines (4 for rare diseases) and new indications in oncology

The AIFA Board of Directors has given the green light to the reimbursement of six new medicines, four of which are for rare diseases, and numerous extensions of indications in the field of oncology. The decisions taken strengthen access to innovative therapies and expand the options available in the National Health Service for people with cancer and patients with rare diseases with high clinical needs.

MEDICINES FOR RARE DISEASES

The innovative orphan drugs that will be reimbursed by the NHS are **Duvyzat** (givinostat), for Duchenne muscular dystrophy (DMD), and **Carvykti** (ciltacabtagene autoleucel) for multiple myeloma.

Duvyzat (givinostat) is a molecule authorised in the European Union in June 2025. Italy will be among the first European countries to make it reimbursable. This medicine is eagerly awaited by the Duchenne muscular dystrophy patient community, especially after the European Commission's decision in March 2025 not to renew the conditional marketing authorisation for the medicine Translarna (ataluren) for the same therapeutic indication, due to a negative benefit/risk ratio.

The other innovative orphan drug is Carvykti (ciltacabtagene autoleucel), a CAR-T cell therapy reimbursed for the treatment of patients with relapsed and refractory multiple myeloma who have received at least one prior therapy and are refractory to lenalidomide. In clinical trials, Carvykti has been shown to significantly reduce the risk of progression or death compared to control arm treatments.

The other two orphan drugs approved for reimbursement are **Akantior** (polyesanide), the first therapy authorised in Europe for the treatment of Acanthamoeba keratitis, and **Yorvipath** (palopegteriparatide), for parathyroid hormone (PTH) replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism, a rare metabolic disease characterised by a deficiency of parathyroid hormone (PTH).

The Board of Directors also gave the green light to two new molecules indicated for use in oncology, 14 therapeutic indication extensions and two generics.

ONCOLOGY DRUGS

The two new **oncology drugs** are:

- **Lazcluze** (lazertinib), for the treatment, in combination with amivantamab, of advanced non-small cell lung cancer.
- **Tevimbra** (tislelizumab), indicated as monotherapy for the treatment of adult patients with unresectable, locally advanced or metastatic squamous cell carcinoma of the oesophagus.

EXTENSIONS OF THERAPEUTIC INDICATIONS

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

- **Darzalex** (daratumumab), two extensions of therapeutic indications for the treatment of multiple myeloma.
- **Eltrombopag Krka** (eltrombopag), for the treatment of primary immune thrombocytopenia (ITP).
- **Jaypirca** (pirtobrutinib), for the treatment of chronic lymphocytic leukaemia.
- **Opdivo** (nivolumab), 3 extensions of indications: 2 in the treatment of urothelial carcinoma and 1 in the treatment of colorectal carcinoma in combination with Yervoy (ipilimumab).
- **Rybrevant** (amivantamab), 3 extensions of indication in the treatment of non-small cell lung cancer.
- **Tevimbra** (tislelizumab), 3 extensions for the treatment of gastric or gastroesophageal junction adenocarcinoma, non-small cell lung cancer and squamous cell carcinoma of the oral cavity.

GENERIC MEDICINES

The 2 generics that will be reimbursed by the NHS are:

- **Lorazepam Macure** (lorazepam), a benzodiazepine in injectable solution indicated as premedication before surgical or diagnostic procedures or for the symptomatic treatment of pathological anxiety and tension in patients unable to take oral medication.
- **Nintedanib Accordpharma** (Nintedanib esilato) indicated in combination with docetaxel for the treatment of adult patients with non-small cell lung cancer.

Finally, the price of **Beleodaq** (belinostat), a medicine not authorised in Italy, was negotiated for inclusion in the list of **Law 648/1996** with the indication for the treatment of adult patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). Beleodaq will therefore also be reimbursed by the NHS.