

Eleanor Butler, Consultant and Joshua Beddow, Junior Analyst at Lightning API review the recent reimbursement of Luxturna in Italy

Luxturna: reimbursement through the Italian fund for innovative oncology medicines



Luxturna is gene therapy, indicated for a small sub-population of retinitis pigmentosa patients who have confirmed biallelic mutations of RPE65 and sufficient viable retinal cells. After gaining landmark EMA approval in November 2018, it is now fully reimbursed in Italy over two years later.

When was Luxturna initially available in Italy?

- Patients first had access to Luxturna in Italy on a named patient basis via the AIFA 5% fund at the start of 2020

Reimbursement

- As of 10th January 2021, Luxturna is fully reimbursed in Italy through the fund of innovative non-oncology drugs with an ex-factory price of €360,000 per patient with mandatory discounts applied at health facilities
- Given the importance of timely access of public health facilities to the fund for innovative medicines, regional representatives must proceed with the qualification of authorised health centres

Payment model

- Luxturna has been approved with a spending cap of €21.6 million (including costs accrued during early access schemes) over a 24-month period
- This means that given the spending cap and the ex-factory price of €360,000, Luxturna will only be reimbursed for a maximum of 60 patients over the 2-year contract (although this does not factor in the obligatory confidential discount, which in practice, would translate to more patients covered within the payment model)

Payback

- If the spending cap threshold is crossed, Novartis will be required to pay back the excess and this will be calculated based on consumption and turnover

What does Novartis need to provide?

- Novartis is obliged to provide sales data relating to products subject to the cap restrictions
- They must also report the consumption trend in the period of the agreement

Advancements in entry agreements

- A different approach has been taken for Luxturna compared to previous high profile ATMPs such as Yescarta and Kymriah (CAR-T therapies) and Holoclax (ophthalmology) which were reimbursed with payment-by-results schemes in Italy
- The scheme proposed for Luxturna reduces manufacturer uncertainty for Novartis regarding price per patient up to the spending cap negotiated with AIFA
- It will be important to monitor this agreement as a new approach to sustainable reimbursement for high cost ATMPs in Italy