UNITED KINGDOM

Recent and planned developments in pharmaceutical policies 2019

Special topic: patient-based reimbursement decisions

CHANGES IN PRICING

Voluntary Scheme for Branded Medicines Pricing and Access 2019
A new voluntary scheme to control the cost of medicines to the National Health Service (NHS) was agreed with industry and introduced on 1 January, replacing the Pharmaceutical Price Regulation Scheme 2014, and introduced on 1 January 2019. This places a cap on sales growth of 2%, with any spend above this level to be paid back to the NHS. For 2019, this means companies will make payments of 9.6% of total relevant sales income.

Statutory Pharmaceutical Pricing Scheme
Regulations came into force on 1 January to amend the Branded Health Service Medicines (Costs) Regulations 2018, which control costs on branded medicines spend not covered by the voluntary scheme. The principal amendment was to revise the payment percentage on net sales income to 9.9% (in 2019), 14.7% (in 2020) and 20.5% (in 2021).

CHANGES IN REIMBURSEMENT

Prescription charge
The prescription charge in England was increased to £9.00 on 1 April 2019 (no charges apply in Scotland, Wales and Northern Ireland).

OTHERS CHANGES

- From 1 November 2018 doctors on the UK's General Medical Council's Specialist Register are able to prescribe cannabis-based products for medicinal use, where clinically appropriate and in the best interests of patients. In the absence of licensed products, products can be imported as an unlicensed 'special' medicine on a named patient basis.
- Regulations came into force on 1st April 2019 that enable NICE to charge companies for making technology appraisal and highly specialised technology evaluation recommendations on their products. The introduction of charging puts NICE's assessment programmes on a more sustainable footing that reduces its reliance on Government funding and enables it to respond to developments in the life science sector.
- NICE has started a review of its technology appraisal and highly specialised technology evaluation methods, a commitment in the 2019 Voluntary Scheme for Branded Medicines Pricing and Access.

SPECIAL TOPIC: patient-based reimbursement decisions

Primary (community) care
Doctors can theoretically prescribe any drug, except those that are blacklisted or have their use restricted via the grey list (both lists are very limited in scope). However, prescribing is also constrained by:
- NICE guidelines and professional guidance which may indicate that certain conditions, including the prescribing of any drugs, should be managed by specialists in secondary care.
- Local formularies, which set out the drugs that the local commissioning organisations have 'approved'.

Where a doctor wishes to prescribe a drug which is not approved for reimbursement, they can submit an individual funding request (IFR) to the local commissioning body. In doing so, they must set out the case why the drug is necessary, e.g. on compassionate grounds on the basis that all other approved treatments have failed.

Secondary (hospital) care
Doctors theoretically have full freedom of prescribing, where any drug prescribed would be reimbursed. However, this is practically constrained in a number of ways by:
- The NICE technology appraisal process
- Commercial access agreements and the Cancer Drugs Fund, which establish the circumstances under which a given high-priced drug can be prescribed
- Regional drug formularies, which set out those drugs which will automatically be reimbursed

As for primary care, a doctor who wishes to prescribe a drug which is not authorised for reimbursement can submit an IFR request to the local commissioning body.