

Original Pack Dispensing (OPD) webinar

Gordon Hockey

Director, Legal

Suraj Shah

Drug Tariff & Reimbursement Manager

Daniel Ah-Thion

Community Pharmacy IT Policy Manager





In this webinar

- Background and aims of OPD +/- 10%
- Regulatory changes
- How will reimbursement work
- IT and EPS
- Summary and Q&A







Background and aims of OPD +/10%

Background of OPD +/-10%

DHSC and MHRA held a public consultation in 2021 with two proposals:

- 1. Enable Original Pack Dispensing (OPD) flexibility to dispense up to 10% more or less of the medicine, compared with the quantity prescribed, if it means that a pharmacist can dispense in the manufacturer's original pack (except where this would negatively affect the patient's clinical treatment regimen)
- II. Mandate whole-pack dispensing of medicines containing sodium valproate

Following the consultation, Government decided to progress these proposals



Aims of OPD

The aims of Original Pack Dispensing (OPD) include:

• increase patient safety by ensuring medicines are provided with a complete pack including a patient information leaflet (PIL), which contains information about the safe and effective use of a product

• improve dispensing efficiency – reduce time splitting boxes, splitting blisters and repackaging medicines to dispense the exact quantity



Regulatory changes

UK legislation to English terms of service (PLPS regs)

- UK legislation: Introduced in Autumn 2023, HMRs apply to private Rx, for POMs
- Sodium valproate: Must be dispensed in the OP unless there are exceptional circumstances – if so, risk assess and ensure PIL supplied. Private and NHS
- PLPS regs: Effective from 1 Jan 2025, for POMs, P meds, and GSLs*







Options – terms of service

- You <u>may</u> supply up to 10% more or less than the quantity prescribed if:
 - an Original Pack (OP) will be supplied
 - the supervising pharmacist considers the patient can still follow the prescriber's directions (medication regimen)
 - otherwise, prescription requirements are complied with
- You may supply the full pack (>10%) if:
 - the product is classed as a 'special container' in the Drug Tariff









Obligations – terms of service

- You the pharmacist <u>must</u> consider, in the exercise of your professional skill and judgement, whether it is reasonable and appropriate [to dispense +/- 10%,] having regard to the benefits to patients where they are provided with drugs in their manufacturer's original outer packaging.
- No obligation to use OPD +/- 10%
- Arguably there is a <u>professional imperative</u> to dispense an OP?
- (You must dispense sodium valproate in an OP*)









Additional changes to special container rules

The regulations on OPD also provide that a prescription-only medicine may be sold or supplied in a different quantity to that on the prescription (> 10%) where the medicine:

- Is in a form that makes it impracticable to dispense the exact quantity (vials);
- Is in a container that has an integral means of application or from which it is not practicable to dispense an exact quantity (inhalers);
- Cannot be dispensed in the quantity ordered without adversely affecting the medicine (hygroscopic medicines)



What does this mean for existing special container rules

- These HMR exceptions now provide a legal basis for pharmacists to supply full packs nearest to the quantity prescribed of a POM (even if it means the quantity supplied falls outside the +/-10% rules)
- DHSC needs to align the current special container rules in the Drug Tariff with the HMR exceptions the list of POM special container products is being reviewed
- Non-POMs are not covered by the above provisions so these may be dealt with differently



Products covered by OPD +/- 10% rules

Product type	Covered by OPD rules
POMs	
Non-POMs (P, GSL, non-medicines including ACBS products, food supplements, cosmetics, toiletries etc.)	
Schedule 5 Controlled Drugs (Sch 5 CDs)	

Note: Whilst the HMRs enable OPD for POMs. Non-POMs are bound by PLPS



Products NOT covered by OPD +/- 10% rules

Product type	Covered by OPD rules
Part IX Appliances (Part IXA, IXB, IXC and IXR)	×
Schedule 1-4 Controlled Drugs (Sch 1-4 CDs)	×
Unlicensed specials (Part VIIIB, Part VIIID and non-Tariff specials)	X
Special Containers*	X
Products supplied in accordance with Serious Shortage Protocols (SSPs)	×
Products supplied in accordance with Patient Group Directions (PGDs)	×

^{*}Changes to special containers rules are being worked on to align with the HMR exceptions



Types of prescriptions covered by OPD arrangements

- For reimbursement purposes, OPD rules will apply to NHS electronic prescriptions only (for eligible items)
- +/-10% OPD rules can be applied to cross-border Welsh electronic prescriptions dispensed in England
- However, +/-10% OPD rules will NOT apply to supplies made against any NHS
 paper prescriptions (this includes any cross-border paper prescriptions issued in
 Northern Ireland, Scotland or Wales and dispensed in England)



Do prescription charges still apply if less is supplied following OPD rules?

- Unless the patient holds a valid exemption reason or the item prescribed is a free-of-charge item, prescription charges are payable for supplies made under +/-10% OPD rules even if this means that a patient is supplied with a smaller quantity of medicine than was originally prescribed.
- (With quantity restriction SSPs (serious shortage protocols) a patient is exempt from paying prescription charges if receiving less than the quantity prescribed).



OPD Reimbursement

How will reimbursement work for OPD?

Community Pharmacy England accepted +/-10% OPD arrangements for NHS dispensing on the basis that:

- pharmacy owners will be reimbursed for the dispensed quantity rather than the prescribed quantity
- no additional endorsements will be required to indicate to the NHSBSA that
 OPD rules have been followed by the pharmacy



How will NHSBSA know if OPD has been used by a pharmacy?

- The dispensed quantity is always populated in the Electronic Reimbursement Endorsement Message (EREM) before an EPS claim is submitted for payment to the NHSBSA.
- To avoid the need for any new endorsements for OPD, it was agreed that the NHSBSA will utilise the existing EPS dispensed quantity field to determine payment.
- All other prescription endorsement requirements remain unchanged.









Reimbursement arrangements

For EPS prescriptions, NHSBSA will capture the dispensed quantity information from the EPS claim message (or EREM) and reimburse as follows:

Scenario	Reimbursed for
If the dispensed quantity is the same as the prescribed quantity	Prescribed quantity
If the dispensed quantity is up to 10% more than the prescribed quantity	Dispensed quantity
If the dispensed quantity is more than 10% of the prescribed quantity	Prescribed quantity
If the dispensed quantity is lower than the prescribed quantity	Dispensed quantity



Rounding rules

Where +/-10% of the prescribed quantity does not result in a whole number, the table below shows how the rounding limits should be applied to allow OPD.

Prescription ordering	10% of the prescribed quantity	Rounding up or down to supply an original pack
28 tablets	10% of 28 = 2.8 tablets	2.8 must be rounded up to 3 to enable pharmacists to provide +/- 3 tablets if it allows supply of an original pack
42 tablets	10% of 42 = 4.2 tablets	4.2 must be rounded down to 4 to enable pharmacists to supply +/- 4 tablets if it allows supply of an original pack
15 tablets	10% of 15 = 1.5 tablets	Following half-way rule, 1.5 must be rounded down to 1 to enable pharmacists to provide +/- 1 tablet, if it allows supply of an original pack

OPD reimbursement examples

Prescription for	10% of the prescribed quantity	Possible supply options	Reimbursement
Paroxetine 40mg tablets x 30	10% of 30 = 3	30 tablets (OPD)	Paid for 30
raroxetine 40mg tablets x 30	10 % 01 30 = 3	28 tablets (OPD)	Paid for 28
Dexamethasone 500microgram tablets	s 10% of 28 = 2.8	28 tablets (OPD)	Paid for 28
x 28		30 tablets (OPD)	Paid for 30
	100% of 50	56 tablets (OPD)	Paid for 56
Perindopril erbumine 8mg tablets x 56	10% of 56 = 5.6	60 tablets (OPD)	Paid for 60
Lacosamide 50mg tablets x 15	10% of 15 = 1.5	15 tablets	Paid for 15
Lacosailine Joing tablets X 10		14 tablets (OPD)	Paid for 14

Non-OPD reimbursement examples

Prescription ordering	Is +/-10% OPD supply permitted?	Possible supply options	Reimbursement
Dipyridamole 200mg modified release capsules x 42	No Special container	60 (or 42 if clinical reason to supply exact quantity)	Paid for 60 tablets
Morphine 60mg modified-release capsules x 56	No Schedule 2 CD	56 (2 x 28)	Paid for 56 tablets
Flunarizine 10mg tablets x 28 tablets	No Part VIIID special	28 tablets (out of pack of 30)	Paid for 28 tablets (BB may be claimed)
GlucoRx Safety lancets x 112	No Part IXA appliance	112 (from a pack of 100)	112 lancets

Container allowance

- Pharmacies receive a container allowance of 10p for every prescription item supplied where the quantity ordered is outside of an available pack size (or a multiple of the pack size).
- Where an original pack is supplied following +/-10% OPD rules, pharmacies will no longer receive the 10p container allowance.
- 10p container allowance will continue to be paid for non-OPD supplies i.e. requiring supply of split packs.



Broken bulk and price concessions

 Broken Bulk (BB) - For non-OPD supplies, BB claims can continue to be made to claim payment for a complete pack of an eligible product where only a part-pack has been dispensed.

 Price concessions – If a pharmacist has correctly applied the +/-10% OPD rules to supply a complete pack of an eligible product, any monthly price concessions granted will apply to the dispensed quantity



IT and EPS:

Navigating the transition to use of OPD in PMRs

OPD enablers



• The legal enabler: DHSC has amended legislation so that OPD must be considered from 1st January 2025 i.e. whether to dispense within the 10% range of the prescribed quantity for relevant items



The technical enabler = PMR readiness: Pharmacy owners must consider OPD from 1st January, but the DHSC and Community Pharmacy England say that it is reasonable for pharmacy teams to decide to **opt out** of using the OPD provisions **until** the clinical support software supports OPD



PMR supplier readiness

Considering OPD use		System OPD status
	Pharmacy team consider or use OPD arrangements	System ready
	Pharmacy team may opt-out from use of OPD until the IT system is ready*	× System unready

^{*}Community Pharmacy England advises caution using OPD if your PMR IT supplier has not confirmed readiness.



A pharmacy team's journey (PMR OPD)

- 1 Preparations prior to yourOPD launch
- Further supplier communications

Supplier work to roll out, and comms to you about readiness

5 Training and process

including cpe.org.uk/opd

8 Refining

- 2 1st January,
 2025
 Consider OPD, but
 can opt-out if PMR
 unready
- 4 Pharmacy
 team decide
 their OPD start
 date
 Pharmacy owner

Pharmacy owner assesses team and system readiness

6 Pharmacy team launches use of OPD

1st Jan or after if PMR is ready later

7 Monitoring usage



PMR OPD roadmap

PMRs communicate about OPD



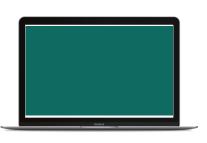
Ongoing supplier testing







PMR OPD: Advanced features (validation)





Validate quantity inputs

The <u>EPS dispensing supplier specification</u> recommends that suppliers include this safety and assistive feature



Provide warnings





Pharmacy team's EPS OPD submission



Populate quantity dispensed field



OPD
endorsement
'flag' not
required



Submit the EPS claim message (EREM)



Overcome the reconciliation challenge:

Why pharmacy teams reconcile payments?



Identify potential errors



Address system, training or process issues



Ensure accurate reimbursement



How to reconcile OPD payments

1. Prescription item report

Register for the <u>NHSBSA's</u> Information Services Portal

3. Identify discrepancies

To ensure accurate reimbursement

2. Access the report

Use the <u>factsheet to assist with</u> <u>access and understanding the</u> <u>report</u>

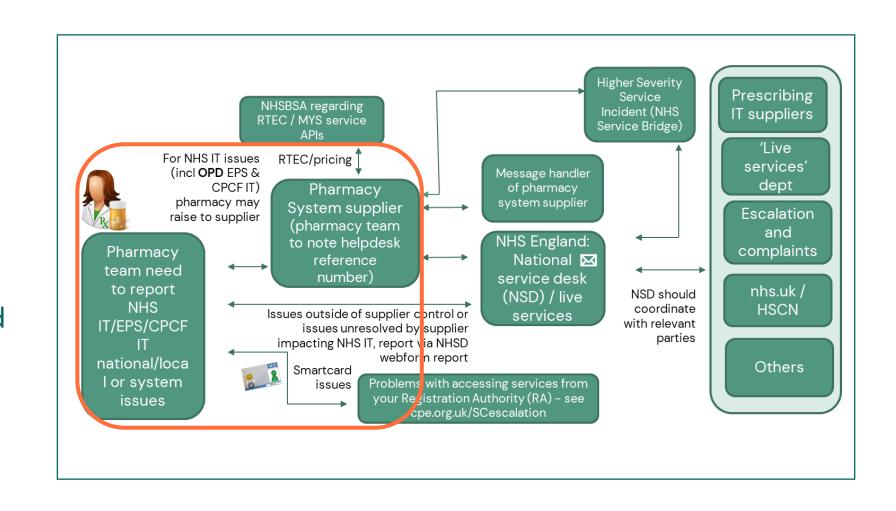
4. Reconcile payments

Use the prescription item report to reconcile the payments



Pharmacy team and supplier collaboration

- Usual escalation applies
- Raise items to supplier
- Use email
- Seek ticket number
- Requests for enhanced
 OPD features
- cpe.org.uk/itreport





Next steps for getting the most from OPD



Subscribe for updates



Monitor supplier communications



Plan for OPD and when you'll start



Explore PMR system changes



Spot check pricing





Summary and Q&A

