

Pharmacy Quality Scheme Medicines safety audits

On 22 July 2019, the [Community Pharmacy Contractual Framework \(CPCF\) for 2019/20 to 2023/24](#) was published by the Department of Health and Social Care (DHSC). This five-year framework contains the new contractual arrangements for community pharmacy and came into force on 1 October 2019. As part of the announced changes, the Quality Payments Scheme (QPS) has been renamed as the Pharmacy Quality Scheme (PQS) and forms part of the CPCF.

The quality criteria for the PQS are bundled within six domains. The domain which includes the patient safety audits builds on the World Health Organization (WHO) Medication Safety Challenge and work that has previously been undertaken as part of the QPS to improve patient safety. This domain has also been aligned to the General Practice (GP) Quality and Outcomes Framework (QOF) Quality Improvement (QI) module. You will need to ensure that your pharmacy achieves **all** the quality criteria within the domain to receive payment. Please find below a summary of the medicines safety audits and the quality criteria that must be achieved within this domain.

Under the PQS, the “Medicines safety audits complementing GP QOF QI module” domain is composed of 3 main parts:

- completion of a lithium, methotrexate, amiodarone OR phenobarbital audit – you are only required to complete one of these audits (please see the ‘Identifying which audit to undertake’ section on the next page)
- completion of a valproate audit
- completion of a non-steroidal anti-inflammatory drugs (NSAIDs) audit, incorporating the findings and recommendations from the previous clinical audit on NSAIDs prescribed for those aged 65 years and above without gastroprotection, undertaken as part of the QPS for the February 2019 review point

All the above must be completed to enable the pharmacy to claim for this domain. If completed successfully this domain is worth 25 points, equating to a minimum payment of £1600.

The questions in the audit data collection sheets have been designed to support conversations between pharmacists and patients and builds on the advice that is already being given.

For all the audits included in these bundles:

- Document if a patient declines a discussion with the pharmacist. This is an important part of your audit submission
- Only document data once for each patient
- Don’t submit patient identifiable data (including patient initials) to the MYS portal



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Lithium, methotrexate, amiodarone or phenobarbital audits.

Meeting the criterion

On the day of the declaration the contractor must submit the data captured in the audit data collection table via the MYS portal.

Recommended reading before initiating audits

The reading to be undertaken will be dependent on which audit is to be undertaken – refer to ‘identifying which audit to undertake’ section below for further guidance.

Lithium - [‘Patient Safety Alert NPSA 2009/PSA005 Safer lithium therapy’](#) [NICE guidance Bipolar disorder: assessment and management, NICE \(2014\)](#)

Methotrexate - [Improving compliance with oral methotrexate guidelines](#) [NICE guidance ‘What monitoring is required for methotrexate’](#)

Amiodarone - [The NPSA Rapid Response Report: Preventing fatalities from medication loading doses](#), [NICE guidance 'How is amiodarone initiated, and what the is the usual maintenance dose?’](#)

Phenobarbital – [Commission on Human Medicines \(CHM\)](#) review of spontaneous adverse drug reactions reported to the MHRA following stabilised patients being switched from branded to generic antiepileptic drugs.

Detailed guidance on completing this audit is provided in the NHS England and NHS Improvement [Pharmacy Quality Scheme Guidance 2019/20](#).

Duration of Audit

Three consecutive months; the 3 months must be completed back-to-back without any break. The latest possible date to start this audit is Friday 29 November 2019 (this will allow contractors to complete their audit, within a three month consecutive period (if the contractor starts the audit when the pharmacy opens on 29 November 2019 and makes their declaration on the final day of the declaration window (28 February 2020) after the pharmacy has closed for the day. However, we recommend that you start the audit as soon as possible to minimise the risk of delays to your PQS declaration.

Identifying which audit to undertake

- 1) Review your patient medication record (PMR) and identify if lithium has been dispensed to any ongoing patients in the 3 months before the audit starts.
- 2) If lithium has been dispensed in the 3 months prior to the audit commencing, the lithium audit should be undertaken.
- 3) If you have not dispensed lithium in the 3 months prior to the audit commencing, then the pharmacy should then undertake steps 1 and 3 for methotrexate then amiodarone then phenobarbital, stopping when once an auditable drug is identified. This priority order must be adhered to, the pharmacy cannot choose which audit to undertake.
- 4) If you haven’t dispensed any of the four auditable drugs in the last 3 months and are unlikely to do so, you should decide on a date to commence the three month audit. Once the audit period is commenced the first medicine to be dispensed of the above four medicines will become your audit drug.



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- 5) If no prescriptions are dispensed for the four auditable drugs during the chosen 3-month period, you will be required to declare this.

The NHSBSA hold information on the number of each of the four auditable drugs dispensed by individual pharmacies during the PQS period and this can be checked as part of post-payment verification.

Audit data collection tables

To aid completion of these audits, the following [audit data collection tables](#) have been created and published by NHS England and NHS Improvement.

[Annex 6](#) – Lithium audit data collection table

[Annex 7](#) – Methotrexate audit data collection table

[Annex 8](#) – Amiodarone audit data collection table

[Annex 9](#) – Phenobarbital audit data collection table

Contractors will also have the choice of using PharmOutcomes to assist them with completing one of the above audits (this is not a requirement of the PQS). This support is available to all contractors free of charge as PSNC has agreed to use their PharmOutcomes licence to provide access to this support. PSNC will highlight when these audits are available on PharmOutcomes through their normal communication channels.

Records

The information from the audit collection table (or from the report which can be printed from PharmOutcomes) will need to be added to the [MYS portal](#) when the pharmacy completes their PQS declaration. If completing the audit using the paper audit data collection tables, it is extremely important to keep these in a safe place when you have finished the audit as you will need this to complete your PQS declaration on the MYS portal.

Some of the detail collected as part of the audit needs to be uploaded to the patient's PMR or appropriate record, the minimum requirements for this are detailed in each data collection table.



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Valproate Audit

Meeting the criterion

On the day of the declaration the contractor must submit the data captured in the audit data collection table via the MYS portal.

Recommended reading before initiating this audit

[MHRA Drug Safety Update 2018](#) including the Guide for healthcare professionals and the Patient Guide.

Detailed guidance on completing this audit is provided by the NHS England and NHS Improvement [Pharmacy Quality Scheme Guidance 2019/20](#).

Duration of Audit

Three consecutive months; the 3 months must be completed back-to-back without any break. The latest possible date to start this audit is Friday 29 November 2019 (this will allow contractors to complete their audit, within a three month consecutive period (if the contractor starts the audit when the pharmacy opens on 29 November 2019 and makes their declaration on the final day of the declaration window (28 February 2020) after the pharmacy has closed for the day. However, we recommend that you start the audit as soon as possible to minimise the risk of delays to your PQS declaration.

Audit data collection tables

To aid completion of this audit, the following [audit data collection table](#) has been created and published by NHS England and NHS Improvement.
[Annex 10](#) – valproate audit data collection table

Supporting resources

This audit requires the pharmacist to check if the patient has been issued with a patient guide and a patient card. These resources can be accessed through the [MHRA Drug Safety Update 2018](#).

Records

The information from the audit collection table (or from the report which can be printed from PharmOutcomes) will then need to be added to the MYS portal when the pharmacy completes their PQS declaration. If completing the audit using the paper audit data collection tables, it is extremely important to keep these in a safe place when you have finished the audit as you will need this to complete your PQS declaration on the MYS portal.

Some of the details collected as part of the audits need to be uploaded to the patient's PMR, the minimum requirements for this are also detailed in the data collection table.



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NSAID Audit

Meeting the criteria:

The pharmacy needs to implement the findings and recommendations from the from the previous clinical audit on NSAIDs prescribed for those aged 65 years and above without gastroprotection, undertaken as part of the QPS for the February 2019 review point.

The pharmacy will be required to declare that they have referred all patients who have been prescribed a NSAID or COX-2 inhibitor without gastro-protection to the GP/ healthcare professional for review.

On the day of the declaration the pharmacist must submit the data captured in the audit data collection sheet via the MYS portal.

Recommended reading before initiating this audit

[The findings and recommendations from the previous clinical audit on NSAIDs prescribed for those aged 65 years and above without gastroprotection undertaken as part of the QPS for the February 2019 review points](#)

[The community pharmacy NSAID safety audit 2019-20](#)

National recommendations as outlined in [NICE guidance CG184](#)

Detailed guidance on completing this audit is provided in the NHS England and NHS Improvement [Pharmacy Quality Scheme Guidance 2019/20](#).

Duration of Audit

Two weeks, providing that the minimum sample size of 10 patients is achieved, if the minimum sample size cannot be achieved in 2 weeks, the audit should be extended to 4 weeks. It is advisable to complete this audit as early as possible to release time closer to the PQS deadline.

Records

Whilst data can be captured and referrals made using PharmOutcomes, the data must be submitted via MYS. If completing the audit using the paper audit data collection table, it is extremely important to keep these in a safe place when you have finished the audit as you will need this to complete your PQS declaration on the MYS portal.

Whilst not a requirement under PQS, it is considered good practice to update the patients PMR to ensure that there is a clear record of the discussion that has been undertaken.

