

Standard Operational Procedure

Managed Entry of New Cancer Medicines or New Indications into Practice

Prescribing Advisory Sub Group

Document Control

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1.0	28 th June 2010	Iona Scott & Mary Maclean
2.0	19 th June 2017	Seonaid McLachlan & Mary Maclean

Changes from Previous Versions

Page/Ref	Change
v2.0 p5-9	Addition of flowcharts to illustrate the pathways involved
v3.0	All references to NICE MTA removed

Related Documents:

Prescribing Advisory Sub Group SOP for Document Management.
Prescribing Advisory Sub Group Terms of Reference

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1 Purpose

This Standard Operating Procedure (SOP) describes the methodology and process for the managed entry of new cancer medicines or other regional developments into clinical practice in West of Scotland Cancer Network (WoSCAN) NHS Boards (NHS Ayrshire and Arran, NHS Forth Valley, NHS Greater Glasgow and Clyde and NHS Lanarkshire).

2 Background

In most cases the process of managed entry of new cancer medicines is supported by national guidance from SMC and SIGN. There are also new treatment developments in cancer that may require a change in prescribing practice but may not be reviewed nationally. This process was previously undertaken individually by NHS Boards across the West of Scotland.

The key drivers for developing a regional process include:

- Inconsistency of advice and funding support between NHS Boards leading to inequity, including treatments recommended by national guidance.
- 'Backlog' of developments awaiting consideration.
- Access to expert advice outside the cancer centre.
- Resources for collating submissions and evaluation.
- Administrative workload for clinicians in submitting case by case requests.
- Pressure on individual cancer care pharmacists outside the cancer centre to advise on individual decisions while awaiting local decisions.

Through the Regional Cancer Advisory Group (RCAG) a regional process was developed in order to minimise variation in prescribing practice and streamline workload. This process is managed by the Prescribing Advisory Subgroup (PASG).

The PASG is a central source of advice on new and new use of cancer medicines. This includes developments recommended through national guidance and other evidence based developments requested by clinicians in the West of Scotland.

3 Scope

This SOP will define the following:

- Regional process for the managed entry of new cancer medicines, this includes developments accepted through national guidance and other evidence based developments.
- Roles and responsibilities of individuals involved in this process.

4 Personnel Involved

This procedure will involve the RCAG Prescribing Advisory Sub Group (PASG), Managed Clinical Networks (MCNs), Beatson site specific teams, Pharmacy Cancer Network and West of Scotland NHS Boards. The chair of the PASG will remain the lead manager throughout this process.

In instances where issues occur or where any part of the process does not adhere to this documented procedure, this should be brought to the attention of the PASG Chair.

5 Stages for Access to a New Cancer Medicine in WoSCAN

1. Europe / UK Stage

European Medicines Evaluation Agency (EMA)/
Medicines and Healthcare Regulatory Authority (MHRA)

2. NHS Scotland Stage

Scottish Medicines Consortium (SMC)

3. Regional (WoSCAN) Stage

RCAG Prescribing Advisory Subgroup

4. Local Stage

Individual Health Board Area Drugs & Therapeutics Committee (ADTC)

Local resource planning process

Formulary status

Licensing process

Medicine requires to demonstrate:

- Quality
- Efficacy
- Safety

Total time from the original patent approval of the new compound to completion of the requirements of the licensing authority may be 10 – 12 years.

Clinical and cost effectiveness review

SMC advice to all NHS Boards, as close as possible to launch

Medicine requires to demonstrate:

- Clinical effectiveness
- Cost effectiveness (value for money)

Time for completion: 3 – 4 months.

Regional practice implications (see appendix 3 for details)

Consultation with local experts/MCNs

Medicine requires to demonstrate:

- SMC acceptance
- Advantage(s) over existing therapy
- Support from local specialists
- Role for medicine in context with existing clinical practice

Treatment protocol/guidelines with care management plan

Budget & service impact analysis (NMR)

Time for completion: 2 – 3 months.

Formulary management

Review and approval of regional guidance
Implementation plan and communication to Prescribers

Referral, as appropriate, to local resource planning process

Time for completion: 1 – 2 months.

Planning and resource management

Financial monitoring

Focus on selected new developments which require managed introduction due to cost, service redesign or other resource implications or deviates significantly from horizon scanning estimate

6 New SMC Advice

SMC accepted advice sent in confidence to PASG Chair and Professional Secretary

Responsible person: NHS GGC Nominated Pharmacist

Consider SMC advice with respect to:

NMR - If NMR required, complete relevant sections (as per [NMR form](#))

Protocol - Consider whether existing protocol could be amended (send final word version) or whether needs new SACT protocol ([template](#)) developed.

Responsible person: PASG secretary (in consultation with PASG Chair and Lead CEPAS pharmacist where required to determine SACT protocol and NMR requirements)

Send email template, SMC advice, NMR and SACT protocol template to Beatson site specific team lead/haemato-oncology MCN lead copying in the MCN Manager, MCN Lead Clinician and MCN Pharmacy Representative

Responsible person: PASG Secretary

Completion of NMR and SACT protocol for PASG (see separate diagram for updated CMGs)

Responsible Person:

Beatson site specific team lead/haemato-oncology MCN lead

- has overall responsibility for ensuring that paperwork is completed and submitted to PASG secretary in time for the PASG meeting and that they (or a consultant colleague) will be in attendance at the meeting to present the paperwork and answer any resultant questions.

- lead on the completion of the NMR (with pharmacy support as required)

- provide a medical check on the completed protocol

MCN Pharmacy Representative

- Ensure that the SACT protocol is completed/updated by themselves or a nominated colleague.

- Ensure that a second pharmacist check is completed.

- Send to Beatson site specific team lead (or nominated colleague) for medical check

Send completed paperwork to PASG Secretary by paperwork deadline date (usually 2 weeks prior to meeting) and confirm attendance to present at meeting.

Please note: Incomplete or late paperwork will not be accepted and item for discussion will be moved to the next PASG meeting. Submissions to the group will be removed from the agenda if the proposer or their representative is not in attendance at the relevant meeting.

Responsible person: Beatson site specific team lead/haemato-oncology MCN lead

Is paperwork complete?

Responsible person: PASG Secretary

N

Return to Beatson site specific team lead

Responsible person: PASG Secretary

Y

Is there email confirmation of attendance to present at the PASG meeting?

Responsible person: PASG Secretary

Y

Add to Agenda for PASG meeting

Responsible person: PASG Secretary

N

Add to agenda for following PASG meeting and inform Beatson site specific team lead and MCN manager

Responsible person: PASG Secretary

7 New Regional Development (Tumour Specific)

Request for change in practice that is either off-label or not expected to be considered by SMC e.g. due to patent expiry

Beatson site specific team lead/haemato-oncology MCN lead to inform PASG Chair/Secretary of new regional development they would like to be considered at next PASG meeting.

Responsible person: Beatson site specific team lead/haemato-oncology MCN lead

Completion of NMR and SACT protocol for PASG (see separate diagram for updated CMGs)

Responsible Person:

Beatson site specific team lead/ haemato-oncology MCN lead

- Has overall responsibility for ensuring that paperwork is completed and submitted to PASG secretary in time for the next meeting and that they (or a consultant colleague) will be in attendance at the meeting to present the paperwork and answer any resultant questions.
- Lead on the completion of the NMR (with pharmacy support as required)
- Provide a medical check on the completed protocol

MCN Pharmacy Representative

- Ensure that the SACT protocol is completed/updated by themselves or a nominated colleague.
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Please note: Incomplete or late paperwork will not be accepted and item for discussion will be moved to the next PASG meeting. Submissions to the group will be removed from the agenda if the proposer or their representative is not in attendance at the relevant meeting.

Responsible person: Beatson site specific team lead/haemato-oncology MCN lead

Is paperwork complete?

Responsible person: PASG Secretary

N

Return to Beatson site specific team lead

Responsible person: PASG Secretary

Y

Is there email confirmation of attendance to present at the PASG meeting?

Responsible person: PASG Secretary

Y

Add to agenda for PASG meeting

Responsible person: PASG Secretary

N

Add to agenda for following PASG meeting and inform Beatson site specific team lead and MCN manager

Responsible person: PASG Secretary

8 New/Revised CMG for consideration at PASG

Identified Clinical Management Guideline that requires review by PASG (See SOP for details)

Responsible person: MCN Manager

New CMG

Identify where there are any SACT recommendations, that these are in line with current practice and that there are supporting SACT protocols (if applicable) in place. If SACT recommendations differ from current practice the CMG must be submitted with the supporting NMR and SACT protocol (see flowchart 1 and 2)

Responsible person: MCN Manager and Beatson site specific team lead/haemato-oncology MCN lead (in consultation with MCN Pharmacy Representative as appropriate)

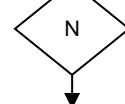
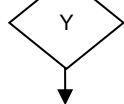
After confirmation that supporting paperwork (if required) has been completed, submit CMG to PASG Chair/Secretary for consideration, naming the consultant oncologist/haemato-oncologist who will attend PASG to present CMG.

Responsible person: MCN Manager (in consultation with Beatson specific site team lead/haemato-oncology MCN lead where additional paperwork also being presented (see page)

Revised CMG

Have there been any changes to SACT recommendations?

Responsible person: MCN Manager and Beatson site specific team lead/haemato-oncology MCN lead

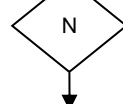
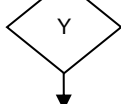


Are these changes in line with either SMC advice/NICE MTA or a regional development that has already been ratified by PASG?

Responsible person: MCN Manager and Beatson site specific team lead/haemato-oncology MCN lead

Send to PASG Chair with summary of changes for Chair's approval

Responsible person: MCN Manager



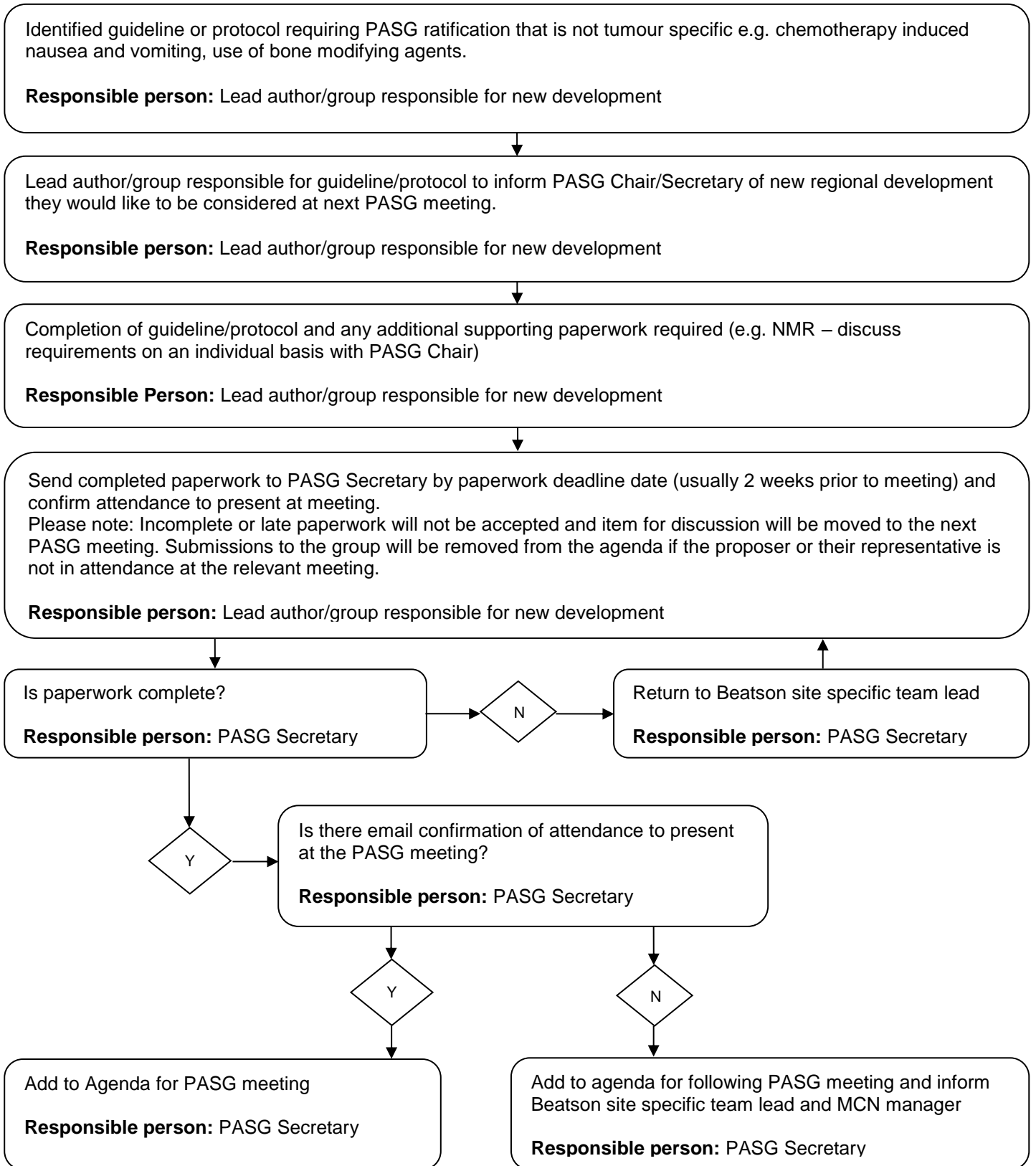
Send to PASG Chair with summary of changes for Chair's approval

Responsible person: MCN Manager

CMG must be accompanied by supporting NMR and SACT protocol (where appropriate) and presented at PASG by a consultant member of the relevant clinical team (see flowchart 1 and 2)

Responsible person: MCN Manager and Beatson site specific team lead/haemato-oncology MCN lead

9 New Regional Development (Supportive Care/Other guideline)



10 Procedure Following Submission to PASG

