GIG CYMRU NHS WALES | Cyd-bwyllgor Comisiynu Joint Commissioning Committee

Appendix 4.4.1

Standard Operating Procedure | Medicines Optimisation: Process for Blueteq Form Development

DRAFT

Version: 0.8

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1. Introduction

Blueteq® is used within NHS Wales to support the appropriate commissioning, monitoring, and reimbursement of high-cost and specialist medicines. For medicines commissioned by the NHS Wales Joint Commissioning Committee (NWJCC), Blueteq® forms are a critical mechanism for ensuring that prescribing aligns with agreed commissioning policies, national guidance, and eligibility criteria.

This Standard Operating Procedure (SOP) describes the agreed process within the Medicines Optimisation team for the development, review, approval, and implementation of Blueteq® forms for NWJCC-commissioned medicines. It provides a structured and auditable approach to form development, ensuring consistency, clinical accuracy, effective version control, and timely "go-live" of forms on the Blueteq® system.

2. Purpose

- Define a standardised process for the development and implementation of Blueteq® forms for NWJCC-commissioned medicines.
- Ensure Blueteq® forms accurately reflect evidence-based guidance (including but not limited to NICE, AWTTC and NHS England clinical commissioning policies), commissioning decisions, and agreed clinical criteria.
- Clarify roles and responsibilities within the Medicines Optimisation team and associated stakeholders.
- Maintain robust governance, version control, and documentation throughout the form development lifecycle.
- Support appropriate medicines use, equitable patient access, and effective monitoring of NWJCC commissioned medicines.

3. Scope

This SOP applies to:

- All Blueteq® forms developed or amended for medicines commissioned by the NWJCC).
- All stages of the Blueteq® form development process, from identification of Blueteq® requirement through to form approval, enablement, and "go-live".
- Members of the NWJCC Medicines Optimisation team involved in drafting, reviewing, approving, and uploading Blueteq® forms.

- Liaison with relevant internal and external stakeholders, including specialist clinicians, finance colleagues, and external bodies (e.g. NHS England, AWTTC), where applicable.

This SOP does not cover:

- Day-to-day use of Blueteq® by provider organisations.
- Clinical decision-making at the point of prescribing.
- Financial processing outside of form enablement and monitoring.

4. Responsibilities

4.1 Medicines Optimisation Support Manager

- Check for existing forms
- Draft initial forms
- Upload forms to Blueteq®
- Enable "go live".
- Ensure version control rules are followed as per this SOP

4.2 Medicines Optimisation Pharmacists

- Review initial drafted forms
- Obtain specialist clinical input
- Implement clinical feedback
- Complete final form enablement check
- Ensure version control is followed as per this SOP

4.3 Lead Pharmacist – Medicines Optimisation

- Oversee process
- Ensure compliance to this SOP

5. Process for Creating Blueteq® forms

5.1 Identify need for Blueteq® form

- Confirm the medicine / indication requires a Blueteq® form

- Add to the Blueteq® Tracker with status: 'in development'.

5.2 Check for Existing Forms

- For each new form:
- Check if an **NHS England** form exists → record **NHSE Form Yes / NHSE Form No** in tracker.
- Check if an **AWTTC** form exists where relevant → record **AWTTC Form Yes / AWTTC Form No** in tracker.
- **If Yes to either:**
  Use the form as the *base template* ("lift and shift").
  If No to both:
  Form must be drafted manually based on guidance and specialist clinical input.

5.3 Draft the Initial Form

- Either "Lift and shift" the NHS England/AWTTC form into an editable **Word document** or contact clinical specialist for input.
- Apply only minimal initial edits:
  - Update title to **NWJCC**.
  - Ensure correct indication, age range, TA number.
  - Routine changes (e.g., adult vs paediatric questions regarding age).
- Save in the correct file structure:
  - **Drug Folder → TA Folder (if multiple) → Word document with versions (v0.1, v0.2, etc.)**
- **Update tracker status to: Drafted Word**

5.4 Pharmacist Review

- Pharmacist reviews the draft (version-controlled, track changes ON).
- Make clinical amendments.
- Save as next version (e.g., v0.2 → v0.3).
- Update tracker status to: **Clinical Review**.

5.5 Obtain Specialist Clinical Input

- Send the draft to relevant clinicians (via email or Teams).
- Specifically ask for comments not track changes.
- Collate clinical comments/approval.

- Update tracker status to: **Specialist Clinical Input.**

5.6 Implement Clinical Feedback

- Pharmacist incorporates clinical comments using tracked changes.
- Save updated version (e.g., v0.4).
- Update tracker status to: **Feedback Implemented**.

5.7 Upload to Blueteq

- Build the form manually on the Blueteq® platform.
- Save as draft within Blueteq®.
- Update tracker status to: **Uploaded to Blueteq®**.

5.8 Final Pharmacist Enablement Check

- Pharmacist checks the built Blueteq® form line-by-line against the Word version.
- If correct → click **Enable**.
- If errors → send back to medicines optimisation support manager to correct and resubmit.
- Update tracker status to: **Approved** (Enabled).

5.9 Form Goes Live

- Update:
    1. Tracker → **Live**
    2. Add to NWJCC website table
    3. Save File structure
- Send communications to distribution list.

5.10 Communications

- Send out communications to all relevant stakeholders for any new, amended or removed Blueteq® forms.

6. Filing

6.1 Version Control Rules

- v0.1 = copy of NHSE / AWTTC template with minimal changes.
- v0.2+ = any further rounds of changes made.
- Each update after consultation = new version (v0.3, v0.4, etc.).
- Only NWJCC pharmacists resolve and accept clinical changes.

6.2 File Structure Format

- Blueteq Form Development Folder
- → Drug Name Folder (e.g., Pembrolizumab)
    1. → TA Number Folder (e.g., TA967)(Where there are more that one per drug)
        1. → v0.1 NWJCC – Form Type (Initial / Continuation) – Medicine generic name + indication (Guidance reference).docx
        2. → v0.2 (as above)
        3. → v0.3 (as above)

7. Process for amending Blueteq® forms.

7.1 Rationale for Blueteq® form amendments

- Changes to national guidance e.g. NICE TA's, AWMSG guidance and amended commercial / marker access arrangements.
- This process is necessary to ensure that NWJCC policy and process is in line with the most up-to-date, evidence-based guidance for commissioning services for the Welsh population.

7.2 How to identify the need to amend a Blueteq® form

- Communications received from NICE or AWMSG within the NWJCC NICE inbox.
- NHS Wales / NICE quarterly meetings.
- AWMSG updates following review periods to guidance as agreed at the Licensed One Wales Medicines Assessment Group (LOWMAG) and One Wales Medicines Assessment Group (OWMAG).

7.3 NWJCC process to amend Blueteq® forms

- Search for updated NHSE forms via the Blueteq® system.
- If an updated form is already developed with amendments, NWJCC would adopt these forms and begin the process, starting as per section 5.2 and finishing at section 6 of this SOP.
- If an updated NHSE form is not available, NWJCC would draft an updated Blueteq® form and start the process from section 5.3 and finishing at section 6 of this SOP.

8. Process for removing Blueteq® forms

8.1 Rationale for Blueteq® form removal

- Medicines are no longer recommended by NICE / AWMSG.
- A treatment is no longer deemed high cost and a Blueteq® form is no longer required.
- A treatment falls within a service which has been decommissioned.
- This process is necessary to ensure that NWJCC policy and process is in line with the most up-to-date, evidence-based guidance for commissioning services for the Welsh population.

8.2 How to identify the need to remove a Blueteq® form from the system

- Communications received from NICE or AWMSG within the NWJCC NICE inbox.
- NHS Wales / NICE quarterly meetings.
- AWMSG updates following review periods to guidance as agreed at LOWMAG and OWMAG.

8.3 NWJCC process to remove Blueteq® forms

- Medicines Optimisation Pharmacist to review updated guidance from the information streams stated in section 8.2.
- To review if patients established on treatment may continue (as per NICE or AWMSG recommendations).
- Review if continuation forms require amendment and carry out process as per this SOP.
- Review and 'disable' initiation forms on Blueteq system if appropriate.
- Amend NWJCC routinely commissioned list to reflect changes.

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Appendix 1

Flow Diagram for Creating a Blueteq® form