CONSULTATION DRAFT

Enclosure No:	XX/XX/XX
Agenda item No:	XX – All Wales implementation framework for biological medicines in COPD
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1.0 Action for consultees

Consultees are asked to consider and comment on the draft document, the *All Wales implementation framework for biological medicines in COPD* and the associated Equality and Health Impact Assessment (EqHIA) form.

2.0 Purpose

The purpose of this document is to support a controlled, clinically led implementation of biological medicines for chronic obstructive pulmonary disorder (COPD) in Wales. This framework has been written by the National Strategic Clinical Network for Respiratory Conditions with the support of the All Wales Therapeutics and Toxicology Centre (AWTTC).

The document is pertinent to the following AWMSG ambitions, set out in the AWMSG Strategy for Wales: 2024–2029:

- Help people in Wales get the best outcomes from medicines
- Enable access to the right medicines at the right time for people in Wales
- Optimise the value that NHS Wales achieves from its investments in medicines

2.1 Process

- June 2026: Draft document considered by AWPAG
- *July 2026: Draft document out for consultation*
- *September 2026: Consultation comments and responses considered by AWPAG for sign-off*
- *October 2026: Document presented to AWMSG for endorsement*

2.2 Consultees

Consultees include, but are not limited to:

- Directors of Pharmacy
- Medical Directors
- Assistant Medical Directors
- Health Board Chief Executives
- Directors of Nursing
- Local Medical Committees
- Directors of Public Health
- General Practitioners Committee (GPC) Wales
- Royal College of General Practitioners (RCGP)
- British Medical Association (BMA) Cymru

- Llais Cymru
- Community Pharmacy Wales (CPW)
- Public Health Wales (PHW)
- Welsh Government
- NHS Wales Joint Commissioning Committee (JCC)
- National Institute for Health and Care Excellence (NICE)
- AWMSG members and deputies
- AWPAG members and deputies

1.0 Purpose

Biological medicines represent an important advance for a defined subgroup of people with chronic obstructive pulmonary disorder (COPD) who have an eosinophilic phenotype and continue to experience exacerbations despite optimal treatment. This framework is intended to support a controlled, clinically led implementation of biological medicines that protects core COPD services while improving safety and maximising the value delivered for people in Wales. The framework is intended to be applicable to all biological medicines recommended for use in COPD.

2.0 Core principles

1. Biological medicine prescribing will be standardised through the use of the Blueteq high cost drug (HCD) system[1].
2. Currently available and prospective biological medicines will be part of the All Wales COPD management and prescribing guideline[2], and must not be a substitute for high-value interventions.
3. Prioritisation criteria will ensure initiation of treatment is suitable and timely.
4. Clinical ownership will remain with local health board COPD teams (led by a clinician with an interest in COPD), with homecare services supporting administration only.
5. Early real-world outcome data will be used to review and inform any necessary refinement of the framework.

3.0 Access criteria

A Blueteq HCD system initiation form must be completed before starting a biological medicine[1]. The relevant biological medicine-specific form has been designed to align with National Institute for Health and Care Excellence (NICE) criteria, with specifications for reporting outcomes within Wales. Accurate capture of diagnosis, phenotype and exacerbation burden details for each person will ensure treatment with a biological medicine is in alignment with current health technology assessment recommendations.

4.0 High-value COPD interventions

When being considered for a biological medicine, patients must have demonstrated:

- appropriate inhaled therapy with documented adherence (> 80% of inhaler pick-ups in the last 12 months) and good inhaler technique documented by a healthcare professional
- evidence of engagement with smoking cessation services (people who smoke are not currently excluded from receiving biological medicines for COPD, but treatment may be delayed whilst they attend smoking cessation services for at least one month)
- pulmonary rehabilitation completion or formal referral
- engagement with seasonal vaccination administration.

5.0 Prioritisation criteria

While the introduction of biological medicines for the treatment of COPD in Wales offers potential benefits, it also poses challenges. The Bevan Commission's Prudent Health Principles[3] have been adopted to guide clinical decision making with respect to prioritisation criteria. If demand exceeds capacity, treatment initiation will be prioritised whilst staying within each biological medicine's NICE recommendations.

6.0 Exclusion criteria

Exclusion criteria for biological medicines are based on clinical study criteria and real-world clinical evidence, and consist of:

- significant frailty or multimorbidity
- life expectancy < 12 months
- significant co-existing lung disease or lung infection needing systemic treatment
- refusal of the patient to adhere to an injection regimen.

7.0 Stopping rules

In addition to any NICE-mandated reviews, early discontinuation should be considered where exacerbation frequency clearly increases after initiation; this will help avoid prolonged ineffective treatment.

8.0 References

1. All Wales Therapeutics and Toxicology Centre. Blueteq high cost drug system information. 2025. Available at: https://awttc.nhs.wales/pages/blueteq-high-cost-drug-system/. Accessed April 2026.
2. Respiratory Health Implementation Group. All Wales COPD management and prescribing guideline. 2025. Available at: https://awttc.nhs.wales/medicines-optimisation-and-safety/medicines-optimisation-guidance-resources-and-data/prescribing-guidance/all-wales-copd-management-and-prescribing-guideline/. Accessed April 2026.
3. Bevan Commission. A prudent approach to health: Prudent health principles. 2015. Available at: https://bevancommission.org/a-prudent-approach-to-health-prudent-health-principles/. Accessed April 2026.