Enclosure No:	2/AWMSG/1226
Agenda item No:	6 – All Wales implementation framework for biological medicines in COPD
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1.0 Action for AWMSG

AWMSG members are asked to consider the *All Wales implementation framework for biological medicines in COPD* for endorsement. Consultation responses received in Summer 2026 and resulting actions are summarised at the end of the document. AWTTC's equality and health impact assessment form is also enclosed.

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–August 2026: Draft document out for consultation
- September 2026: Consultation comments and responses considered by AWPAG for sign-off
- *December 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 uncontrolled chronic obstructive pulmonary disorder (COPD) with raised blood eosinophils who 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 (see section 4.0).
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 (which cannot be waived), 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:

- comorbidities requiring optimisation before starting a biological medicine, or clinical circumstances where a comorbidity affects treatment appropriateness
- significant frailty (e.g. a Clinical Frailty Scale score of six or more) – should prompt individual review rather than act as an automatic exclusion*
- life expectancy that is unlikely to exceed 12 months
- significant co-existing lung disease or lung infection needing systemic treatment (e.g. clinically important bronchiectasis with recurrent infection, active pulmonary infection or fibrotic interstitial lung disease, particularly where another condition may be the main cause of exacerbation-like events)
- refusal of the patient to adhere to an injection regimen.

Presence alone of one or more factors is not an automatic exclusion to treatment with biological medicines, prompting instead a benefit-risk assessment. When clinically appropriate, the specialist COPD multi-disciplinary team may approve treatment with biological medicines by exception, ensuring the decision rationale has been documented.

* Clinical Frailty Scale has not been widely validated for younger people or people with learning disabilities; it may also be misleading when used for people with stable long-term disabilities such as cerebral palsy.

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. A safety and treatment-support review at 6 months, followed by a formal review at 12 months (NICE-mandated), is intended to ensure treatment with a biological medicine remains appropriate for each patient.

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.

All Wales implementation framework for biological medicines in COPD
Consultation responses

Respondent (title, department and health board) and DOI (chase if not provided)	Page/section	Comment	Response and action taken
David Clough Betsi Cadwaladr UHB	Is there anything you would like to see added to the document?	'People aged over 35 years who present with one or more features from the COPD likelihood checklist should have post-bronchodilator spirometry'. To confirm a COPD diagnosis the post-bronchodilator FEV1/VC ratio should be <LLN (Respiratory Health Implementation Group. All Wales COPD management and prescribing guideline. 2025).	Thank you. This is the definition for COPD and part of the prescribing pathway which will be updated in due course. The National Operational pathway which is currently being finalised will discuss the merits of LLN Vs fixed ratio.
Gareth Dyton Cardiff and Vale UHB	Is there anything you would like to see added to the document?	Within the High Value COPD Interventions section, I believe that Compliance with Non-Invasive Ventilation, if on treatment should be included as a criteria	Thank you for this comment. While we agree that NIV compliance is important, we don't think this is integral to decision making around a treatment that influences exacerbation frequency.
Respondent 1 Hywel Dda UHB	Section 3.0	Would it not be beneficial here to clarify the exact criteria of those who would be eligible for consideration. 1) Considering how far back we look at eosinophils 2) historic asthma that now has a fixed airways needs to be considered on bluetec form	Thank you. It is not possible with current evidence to give a time scale on how far back to look at historic eosinophil counts. This will be at the discretion of the COPD HCP decision maker and may well be part of an MDT discussion either locally or nationally. If the diagnosis is that of asthma (historic or not) this should be referred to the asthma MDT or at least discussed at MDT level. This will also be highlighted on the updated prescribing pathway.
	Line 47	What about those excluded from PR because of physical disability?	Thank you. Inability to undertake pulmonary rehabilitation because of physical disability or another valid clinical reason will not automatically preclude biological treatment. The purpose of this criterion is to ensure that pulmonary rehabilitation has been considered and offered where appropriate.
	Line 48	Please clarify which vaccinations they must be receiving? COVID, influenzas, RSV? And what about those who decline because of adverse side effects/allergies	Thank you. This pertains to all recommended vaccines including influenza, Covid (where applicable) and RSV (again if applicable). Vaccination should be offered and encouraged because it is an important component of exacerbation prevention. However, a contraindication, previous significant adverse reaction or another valid clinical reason for not receiving vaccination will not automatically preclude treatment. The specialist COPD MDT may approve treatment by exception, with the reason and decision documented.

	Line 62	What specifies multi morbidity, would this be two additional consitions to avoid post code lottery i think a more specific criteria are required. Would hypertension and cardiac failure exclude them. Or diabetes and hypertension? Knowing exacerbations increase Cardiovascular risk would it not make sense to give biologics despite a cardiovascular condition?	Thank you. Multimorbidity should not be defined simply by counting conditions, and common well-managed conditions such as hypertension, diabetes or cardiovascular disease will not automatically exclude treatment. The criterion is intended to prompt consideration of whether frailty or comorbidity materially affects safety, treatment burden, ability to engage with treatment or the likelihood of meaningful benefit. Where the specialist COPD MDT considers that biological treatment remains appropriate, treatment may be approved by exception and the rationale documented.
	Line 63	Will the blue tec form require the clinician to state life expectancy exceeds 12 months?	Thank you. It is likely to change to: “Life expectancy > 12 months deemed unlikely” – see below.
	Line 71	Early discontinuation? Are we advising review at 3 months? 6 months? One year. Do we offer the second biologic at that point?	Thank you. There will be reviews at 6 and 12 months – this can be included in the stopping rules and can be discussed at AWPAG meeting. There is currently insufficient evidence to recommend routine switching between COPD biologics after non-response; any future switching policy should follow future NICE/AWMSG advice and specialist MDT review.
	general	If we are expecting CNS teams to identify and manage these patients, consultants will not want every query being discussed with them, so the clearer and more detailed the reports the easier it will be for all clinical staff to initiate and be a more efficient service.	Thank you. Clinical accountability should remain with a respiratory physician with a specialist interest in COPD. Identification, assessment, education, administration and structured follow-up may still be undertaken by members of the multidisciplinary COPD team. Cases meeting the standard criteria should not require repeated discussion of every operational step, while exceptions should be considered by the specialist COPD MDT and documented.
Claire Hurlin Hywel Dda UHB	Page 3 exclusions	2nd bullet point needs explaining it say 'is deemed unlikely'	Thank you – we are happy to discuss at AWPAG meeting and amend to: “Life expectancy > 12 months deemed unlikely”. The specialist COPD MDT may approve treatment by exception where it considers biological treatment clinically appropriate, with the rationale documented.
	Page 4 2nd bullet point	Says refusal of the patient to adhere to twice weekly injection regime - apologies if I am wrong but I thought it was either one very 2 week's or once every 4 weeks depending on drug?	The current version of the document (which was circulated for consultation) states, ‘refusal of the patient to adhere to an injection regimen’ and does not give any frequency since the dosing regimens are different for the two licensed biologic agents.
	Page 4 in stopping rules	NIVCE mandated 12 month review but early discontinuation should be permitted where exacerbation frequency clearly deteriorates after initiation. Could we be clearer on what is meant by early review ? 3 months, ?6 months???	Thank you. We are happy to include reviews at 6 and 12 months – again to discuss at AWPAG as above.

Respondent 2 Chiesi Ltd. *(DOI - represents Chiesi Ltd.)*	Is there anything you would like to see added to the document?	We believe it would be helpful for the framework to provide more specific recommendations relating to the population of COPD patients in which biologic therapy may be considered appropriate. Clearer eligibility criteria would support consistent implementation in clinical practice. For example, international recommendations in the GOLD Report 2026 suggest consideration of biologic therapy in COPD patients with: o ≥2 moderate/ ≥1 severe exacerbations in the previous year; o ≥300 eosinophils/µl; and o Prior treatment with triple therapy (ICS+LABA+LAMA)	Thank you. We could potentially add this to the framework but this may change depending on future biologics. For discussion at AWPAG.
	Framework; page 1: section 4, line 39-48	We appreciate the commitment towards ensuring that the fundamentals of COPD care (appropriate inhaler adherence, smoking cessation, pulmonary rehabilitation, vaccination) are addressed prior to escalation to biologic therapy.	Thank you for this response.
Respondent 3 GSK *(DOI - I am employed by GlaxoSmithKline (GSK). GSK markets mepolizumab and has an interest in the management of patients with COPD who may be eligible for biological therapies. The comments provided relate to the implementation framework and are intended to support clarity, consistency and equitable patient access within the proposed pathway.)*	Is there anything you would like to see added to the document?	We would welcome additional clarification in several areas of the framework. Specifically, it would be helpful to provide greater detail regarding treatment review and discontinuation criteria, including timing of review, definitions of response and deterioration, and how these align with NICE criteria and Blueteq processes. Clarification would also be welcomed that optimisation measures such as smoking cessation support, pulmonary rehabilitation and seasonal vaccination are intended to support high-quality COPD care and should not unintentionally delay access to biological therapy for otherwise eligible patients. Finally, consideration could be given to expanding the description of homecare services to reflect the broader support they can provide, including treatment delivery, injection training, patient education and support for self-administration. **Further detail is provided in the comments below.**	Thank you. We have replied to specific comments below. We agree that the framework should distinguish the formal 12-month NICE assessment from earlier safety and treatment-support reviews, and that the potential practical role of homecare may be described more fully however this will subject to local arrangements and may differ according to each health board. The high-value COPD interventions and suitability criteria are intended to support comprehensive assessment, not to create inflexible barriers. Where a patient meets the drug-specific NICE criteria but cannot satisfy an additional criterion for a valid clinical or practical reason, the specialist COPD MDT may approve treatment by exception and document its rationale.
	Is there anything you would like to see removed from the document?	We suggest reconsidering the broad exclusion criteria relating to “significant frailty or multimorbidity” in their current form. Multimorbidity is highly prevalent in people living with COPD and patients with co-existing medical conditions were represented in Phase 3 COPD biologics trials. Rather than focusing on the presence of frailty, multimorbidity or co-	Thank you. The All Wales Respiratory Network felt that frailty, multimorbidity and co-existing lung disease are clinically relevant and should remain part of the assessment. However, their presence alone is not an automatic exclusion to biologic therapy. The purpose of these criteria is to consider whether the condition materially affects safety, treatment burden, ability to engage or the likelihood of

		existing conditions alone, consideration could be given to whether these factors materially affect treatment suitability, safety, expected benefit, ability to engage with treatment, or whether optimisation is required before treatment initiation. Additional clarification regarding “significant co-existing lung disease” may also help support consistent interpretation and application of the framework. **Further detail is provided in the comments below.**	meaningful benefit. The specialist COPD MDT may approve treatment by exception where it considers biological treatment appropriate, with the clinical reasoning documented.
	Section 7.0: Review and stopping criteria	Section 7.0 introduces an early discontinuation criterion where exacerbation frequency "clearly increases" following treatment initiation. Clarification would be welcomed regarding the intended review timepoint, what constitutes a "clear increase", whether this relates to moderate exacerbations, severe exacerbations or both, and the comparator period used. NICE technology appraisal guidance already specifies a 12-month response assessment and stopping criteria, and NHS England implementation guidance is similarly based around structured efficacy reviews at 12 months. Clarification would therefore be helpful regarding the rationale for introducing an additional early discontinuation criterion and how this aligns with established national review processes. As the framework proposes the use of Blueteq to support standardised implementation and adherence to NICE criteria, further clarification regarding how this stopping rule will operate alongside Blueteq approval and how review processes would support consistent treatment decisions and interpretation of real-world outcomes across Wales. Consideration should also be given to seasonal variation in COPD exacerbation risk. Patients initiating biological therapy shortly before or during winter may have a higher background risk of exacerbation than those initiating during summer. Without a clearly defined review period and comparator, early discontinuation criteria could inadvertently create inequity in the opportunity for treatment to demonstrate benefit. Clear, aligned stopping criteria are also important for real-world data interpretation (e.g. NRAP). If stopping rules are	Thank you. We propose a review at 6 months and 12 months. Biologics should be discontinued if, at review, the number of severe exacerbations is higher than compared with the preceding 12 months of treatment, or the number of severe exacerbations is the same as the 12 months preceding but the number of moderate exacerbations is higher. Earlier stopping remains appropriate for adverse effects, patient preference or exceptional deterioration (so more exacerbations in a 6-month period Vs a 12-month period) after alternative causes and seasonal/contextual factors have been considered and the specialist COPD MDT has reviewed the case.

		interpreted differently across health boards, this may affect the consistency of treatment persistence and outcomes data. Alignment of treated populations and continuation criteria will be important if real-world outcomes are used to review and refine the framework.	
	Section 4.0: High-value COPD interventions	Smoking cessation support is an important component of COPD care and should be routinely offered. However, the framework should clarify that engagement with smoking cessation services should not create an additional barrier or delay to biological therapy for patients who otherwise meet NICE eligibility criteria. This is particularly relevant for patients who have previously engaged with smoking cessation support, where further referral may not be appropriate or may delay treatment initiation. Pulmonary rehabilitation is an important intervention for many patients with COPD, but referral or completion may not always be clinically appropriate, may have been previously attempted, may be declined by the patient, or may be affected by local service capacity and waiting times. Similar considerations may apply to seasonal vaccination. The framework should clarify that these interventions are intended to support optimisation of COPD care and should not unintentionally delay access to biological therapy for otherwise eligible patients. Furthermore, the framework specifies >80% adherence based on inhaler collection. Clarification would be welcomed regarding how secondary care MDTs and prescribers will routinely assess this criterion in practice. Given that prescribing and dispensing data may not always be easily accessible within secondary care systems, are the authors confident that this information can be consistently and reliably obtained across all health boards without creating an additional barrier to assessment and treatment initiation?	Thank you. Smoking cessation support, pulmonary rehabilitation, vaccination and inhaler optimisation remain important components of high-quality COPD care and should normally be addressed before escalation to biological therapies – this was the view of the All Wales Respiratory Network. They are not intended to create an absolute barrier or unnecessarily delay treatment in an otherwise eligible patient. Previous participation, physical inability, clinical unsuitability, contraindication, informed refusal or lack of reasonable access may provide a valid explanation for an intervention not being completed. In these circumstances, the specialist COPD MDT may approve treatment by exception and document the circumstances. Prescription collection data is available through the Welsh Clinical Portal and clarification can always be sought from primary care if needed.
	Section 6.0: Exclusion criteria	The wording “significant frailty or multimorbidity” would benefit from substantial clarification. Multimorbidity - the presence of two or more comorbidities (NICE) - is highly prevalent in people living with COPD and, in isolation, should not necessarily indicate that a patient is unsuitable for	Thank you. Multimorbidity is certainly common in COPD and we agree should not, in itself, exclude treatment. The criteria relating to frailty, comorbidity and co-existing lung disease are intended to prompt an individual assessment of diagnostic certainty (what respiratory conditions are driving symptoms and exacerbations), safety, treatment

		biological therapy. A broad exclusion based on multimorbidity may risk excluding patients who are representative of real-world COPD populations and of populations included in Phase 3 COPD biologics trials. We suggest reframing this criterion to focus on the impact of comorbidities or frailty on treatment suitability, safety, expected benefit or ability to engage with treatment, rather than the presence of frailty or multimorbidity alone. For example, the framework could refer to comorbidities requiring optimisation prior to treatment initiation, or clinical circumstances where a comorbidity materially affects the appropriateness of biological therapy. Further clarification would also be welcomed regarding the exclusion criterion relating to “significant co-existing lung disease”. Additional definition or examples may help support consistent interpretation and application across Wales, particularly where co-existing respiratory conditions are present.	burden and the likelihood of meaningful benefit. Relevant examples of co-existing lung disease include clinically important bronchiectasis with recurrent infection, active pulmonary infection or fibrotic interstitial lung disease, particularly where another condition may be the main cause of exacerbation-like events. The specialist COPD MDT may approve treatment by exception where treatment remains clinically appropriate, with its reasoning documented. The framework will be clarified following AWPAG discussion.
	Section 2.0: Role of homecare services	The framework states that homecare services will support administration only. This may unintentionally narrow the perceived role of homecare. We suggest clarifying whether homecare services may also support treatment delivery, injection training, patient education or support for patients who are initially unable or not confident to self-administer. Clarification would be helpful to ensure that homecare is not limited only to administration for patients who cannot self-inject but can also support appropriate training and transition to self-administration where clinically suitable and preferred by the patient. Clinical ownership should remain with specialist COPD teams, but the framework should reflect the broader practical support that homecare may provide.	Thank you. We agree. Subject to the services commissioned locally, homecare may support medicine delivery, initial and refresher injection training, patient education, adherence support and transition to self-administration, as well as administration for people unable to self-inject. Clinical assessment, prescribing, outcome monitoring and decisions to continue or stop treatment remain the responsibility of the specialist COPD team.
Emma Mistry PCIC, Cardiff and Vale UHB	2/6/62	How should ‘significant frailty’ be assessed? Should a validated clinical tool such as the Clinical Frailty Scale be used?	Thank you. The Clinical Frailty Scale may support a holistic assessment when used in an appropriate population and against the patient's stable baseline, but a score of 6 or more should prompt individual review rather than act as an automatic exclusion. It may be misleading in younger people or those with stable disability or learning disability. Where the specialist COPD MDT considers that a patient is

			likely to derive meaningful benefit despite greater frailty, treatment may be approved by exception and the rationale documented.
William Batten Aneurin Bevan UHB	Is there anything you would like to see added to the document?	Nil – no engagement from clinicians	Thank you for this response.
	Is there anything you would like to see removed from the document?	Nil – no engagement from clinicians	Thank you for this response.
Respondent 4 Sanofi *(DOI- I am an employee and represent Sanofi UK, the marketing authorisation holder for dupilumab (Dupixent).)*	Is there anything you would like to see added to the document?	**Given that the All Wales Implementation Framework aims to align biological medicine treatment with current health technology assessment recommendations, it would be helpful to directly specify the relevant NICE biologic recommendations concerning patient population and eligibility criteria for each biologic, as a clear and directly implementable framework for Blueteq and associated Welsh Guidelines.** **For dupilumab this would be:** **COPD in adults who are on** • maintenance triple therapy, or double therapy where ICS is not appropriate • with uncontrolled disease defined as one or more severe exacerbations or two or more moderate exacerbations in the previous 12 months and a blood eosinophil count of 300 cells per microlitre or more.	Thank you. We could potentially add this detail to the framework but this may change depending on future biologics. For discussion at AWPAG.
	Is there anything you would like to see removed from the document?	**1. The CD (line 4) refers to biologics for a population with "COPD with an eosinophilic phenotype," while the EqHIA form (sections 2 and 3) describes "COPD with an inflammatory (eosinophilic) phenotype".** a. These descriptions may be too narrow to capture the full scope of current NICE-recommended biologics, and may not remain suitable if future biologics are recommended for a broader or different COPD population. b. The populations covered by current recommendations may be more appropriately	Thank you. 1. We agree that terminology should be consistent. To remain closest to NICE and avoid broadening eligibility beyond the evidence, we propose 'uncontrolled COPD with raised blood eosinophils'. 2. Smoking cessation, pulmonary rehabilitation, vaccination and inhaler optimisation are important components of good COPD care and should normally be addressed before biological treatment. They are not intended to act as inflexible barriers where an intervention is contraindicated,

		described as 'COPD with a Type 2 inflammatory phenotype', in which eosinophils serve as a biomarker of broader Type 2 inflammation rather than necessarily being the primary driver of disease. **2. The Consultation Draft aims to align biological medicine use with current health technology assessment recommendations and should therefore support the adoption only of criteria specified by the NICE recommendations. Several additional eligibility criteria set out in the CD (lines 37-48) may not be supported by the evidence base or NICE cost-effectiveness assessments. Requiring arbitrary thresholds, engagement, completion and documentation of these could create avoidable barriers to access for some people with COPD, particularly those affected by frailty, mobility and travel limitations, limited carer or family support or social isolation, and may raise equity issues relevant to EqHIA questions 5.1, 5.2, 5.12, 6.1 and perhaps 6.2 and 6.4.** c. While good inhaler adherence and technique are important when considering add-on biologics, real-world evidence suggests these are not always achievable, even with strong patient engagement. d. Smoking cessation, pulmonary rehabilitation, and seasonal respiratory virus vaccination all provide important health benefits or reduce risks and should be strongly recommended, but may not be practical or accessible for every patient. • Comprehensive provision of these measures is far from being achieved currently. For example, an Asthma & Lung UK survey suggests that only 48% of eligible patients nationally have ever received pulmonary rehabilitation, and among those who have not, 70% were never offered the opportunity. **Given that these additional measures are not consistently available and may be impractical or impossible for some patients to complete, the introduction of effective new medicines should not be**	declined after informed discussion, previously completed, inaccessible or clinically inappropriate. In such circumstances, the specialist COPD MDT may approve treatment by exception and document its rationale. 3. We do not agree that all criteria beyond the NICE wording are arbitrary or unsupported. For dupilumab, chronic bronchitis and a post-bronchodilator FEV1 >30% and <=70% predicted were inclusion criteria in the pivotal BOREAS and NOTUS trials and therefore define the population in whom efficacy was demonstrated. They are trial-derived evidence criteria rather than explicit NICE or marketing-authorisation requirements and should normally guide selection. A patient who meets the NICE recommendation and licensed indication but falls outside a trial-derived criterion may be considered exceptionally by the specialist COPD MDT, with the reason and uncertainty of extrapolating beyond the trial population documented. Frailty, multimorbidity, co-existing lung disease and limited life expectancy should likewise prompt individual benefit-risk assessment rather than automatic exclusion. The MDT cannot waive mandatory drug-specific NICE or licensed requirements.

		contingent upon them; they would be better framed as supportive recommendations rather than mandatory eligibility requirements. **3. The CD (lines 58–66) proposes additional exclusion criteria that are not based on NICE recommendations, but instead on clinical study criteria and real-world clinical evidence. While clinical trials often exclude certain higher-risk patients to protect participant safety and study integrity, it would inappropriate to use trial exclusion criteria to deny real-world access to medicines, from which these patients may also benefit. Indeed, these groups may have the greater unmet need for effective treatment.** e. Significant frailty and multimorbidity are common in COPD and should not, in themselves, be reasons to withhold treatment. They may also reflect COPD progression, which is often driven by worsening exacerbation frequency and severity. f. Similarly, a life expectancy of less than 12 months may in part reflect the predicted burden of future exacerbations and poor lung function. There is evidence for exacerbation risk reduction with NICE recommended biologics, alongside evidence of improved lung function with dupilumab. **Although the challenges of balancing demand and capacity in the short term are understood, it is important that the CD - and the associated Blueteq and Guidelines – look to the future and do not embed practice that excludes the most unwell people from new medicines. Additional exclusion criteria should therefore not be applied in the absence clear evidence that these patients would not benefit or could be harmed by treatment. Instead, the respiratory clinician and MDT are best placed to make informed multi-factorial treatment decisions for complex patients.**	
	Lines 27-34	The Blueteq HCD system appears appropriate, but care is needed to ensure NICE recommendations are transposed accurately.	Thank you. We agree that the drug-specific NICE eligibility and stopping criteria must be transposed accurately. The intention is to support consistent and prudent implementation rather than redefine

			the NICE-recommended population. A specialist COPD MDT can approve an appropriate case by exception, with the clinical circumstances and MDT discussion documented. The framework should make this distinction explicit: the MDT may exercise discretion over additional local implementation criteria but cannot waive the drug-specific NICE eligibility or stopping criteria.
	Lines 49-55	The CD states that patient prioritisation may be necessary to mitigate implementation challenges, in line with the Bevan Commission's Prudent Health Principles. However, the proposed prioritisation criteria are unspecified. If they follow the same approach as the additional eligibility and exclusion criteria set out in the CD, there is a risk of introducing further inequity and non-evidence-based restrictions to access.	Thank you. The intention is to support safe and manageable COPD biologic service, without overwhelming an already fragile health service. Where temporary prioritisation is required because of capacity, it should be transparent, time-limited and based on clinical urgency or anticipated absolute benefit, for example a recent severe exacerbation, especially where there is a risk of further hospitalisation due to an exacerbation. The COPD MDT will retain discretion to consider individual circumstances, including cases that do not fit the usual prioritisation criteria, with its decision documented. Prioritisation must not alter the underlying NICE eligibility criteria.
	Lines 69-73	The CD recommends additional assessment when considering early discontinuation "where exacerbation frequency clearly increases after initiation". For clarity, it may be helpful to specify that early discontinuation should be considered where early exacerbation numbers exceed the patient's historical exacerbation numbers, which would have in any case then been captured by the NICE 12-month assessment.	Thank you. We agree – for discussion at AWPAG.

AWTTC
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan
All Wales Therapeutics & Toxicology Centre

DRAFT

Equality and Health Impact Assessment
All Wales implementation framework for biological medicines in COPD

AWTTC will fill in an Equality and Health Impact Assessment in parallel with each development stage of our projects. This will help us to follow the five ways of working for public bodies, and work to achieving the wellbeing goals, outlined in the Well-Being of Future Generations (Wales) Act 2015.

Date: 04/11/2026

1.	**AWTTC contact details**	Tel: 02921 826900 Email: awttc@wales.nhs.uk
2.	**Objectives of the project**	The purpose of this framework is to support a controlled, clinically led implementation of biological medicines for a subgroup of people with uncontrolled chronic obstructive pulmonary disorder (COPD) with raised blood eosinophils who continue to experience exacerbations despite optimal treatment. This document provides advice to clinicians with an interest in COPD and their local COPD team on introducing biological medicines for this indication to their practice. Clinical ownership will remain with local health board COPD teams (led by a clinician with an interest in COPD).

3.	**Evidence and background information considered** For example: • population data • staff and service users' data, as applicable • needs assessment • engagement and involvement findings • research • good practice guidelines • participant knowledge • list of stakeholders and how stakeholders have engaged in the development stages • comments from those involved in the designing and development stages Population pyramids are available from Public Health Wales Observatory.	This framework has been written by the National Strategic Clinical Network for Respiratory Conditions with the support of AWTTC. The arrival of biological medicines that target inflammatory signals offers a new treatment option for COPD with an inflammatory (eosinophilic) phenotype, which results in frequent exacerbations despite optimal treatment. This framework has been developed to ensure that the challenges related to the introduction of biological medicines into existing COPD treatment pathways in Wales are carefully considered and successfully navigated. The Blueteq high cost drug (HCD) system will allow biological medicine prescribing for this indication to be standardized across Wales.
4.	**Who will this project affect?**	People with this particular phenotype of COPD, local health board COPD teams (including clinicians), pharmacy and homecare services may be affected.

5. EQIA – How will the project impact on people?

Questions in this section relate to the impact on people based on the 'protected characteristics' of the Equality Act 2010, and other factors.

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/mitigation	Actions taken (and who by).
5.1 Age For most purposes, the main categories are people aged: • under 18 years; • between 18 and 65 years; • over 65 years.	We do not expect a potential negative, or unequal, impact on people based on their age. Note: For prescription medicines we expect the prescriber to have prescribed or advised their use within the terms of their UK marketing authorisations. Healthcare professionals should take note of the contraindications, warnings, safety recommendations and any monitoring needs for the medicine. These are explained in the Summary of Product Characteristics (SmPC) for the medicine or the British National Formulary. Healthcare professionals should follow relevant professional guidance and take full responsibility for the decision when prescribing or advising the use of off-label or unlicensed medicines. This includes considering the contraindications, warnings, monitoring requirements and other safety recommendations for the medicine (MHRA guidance on off-label or unlicensed use of medicines)	N/A at this stage	N/A at this stage

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/mitigation	Actions taken (and who by).
5.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes.	We do not expect a potential negative, or unequal, impact on people with a disability.	All related documents published on the AWTTC website will meet accessibility requirements.	N/A at this stage
5.3 People of different genders: Consider men, women, people undergoing gender reassignment. **N.B.** Gender reassignment is a process by which a person proposes, starts, goes through or completes a change to his or her gender with or without going through any medical procedures.	We do not expect a potential negative, or unequal, impact on people based on their gender, or on people undergoing gender reassignment.	N/A at this stage	N/A at this stage
5.4 People who are married or who have a civil partner.	We do not expect a potential negative, or unequal, impact on people based on their marital status or being in a civil partnership.	N/A at this stage	N/A at this stage
5.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	We do not expect a potential negative, or unequal, impact on women who are expecting a baby, are breastfeeding, or are on a break from work after having a baby.	Prescribers should take account of the SmPC when prescribing any medicines for women who are pregnant, or who are breastfeeding.	The SmPC criteria specify which people are excluded from treatment due to the associated risks of treatment.

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/mitigation	Actions taken (and who by).
5.6 People according to their race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies and travellers, migrant workers. The Runnymede Trust	We do not expect a potential negative, or unequal, impact on people of a different race, nationality, colour, culture or ethnic origin. People of different races and ethnicities can have varying responses to medicines.	N/A at this stage	N/A at this stage
5.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief. Implications of religious beliefs on selection of medicines (BMJ) In practice: guidance on religion, personal values and beliefs (General Pharmaceutical Council)	We do not expect a potential negative, or unequal, impact on people who have a religion or belief, or people with no religion of belief. Some medicines are made from certain animal products and people might not want to take them because of religion or belief.	N/A at this stage	N/A at this stage
5.8 People who are attracted to other people of: • the opposite sex (heterosexual); • the same sex (lesbian or gay); • both sexes (bisexual). Stonewall	We do not expect a potential negative, or unequal, impact on people based on who they are attracted to.	N/A at this stage	N/A at this stage

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/mitigation	Actions taken (and who by).
5.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design.	We do not expect a potential negative, or unequal, impact on people who communicate using the Welsh language.	Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets, where appropriate. These will be provided on the AWTTC website in accessible formats that can be printed.	N/A at this stage
5.10 People according to their income related group.	We do not expect a potential negative, or unequal, impact on people based on their income-related group. In Wales, all prescription medicines are free-of-charge for patients; positive recommendations through this project will not affect people depending on their income-related group.	N/A at this stage	N/A at this stage
5.11 People according to where they live.	We do not expect a potential negative, or unequal, impact on people based on where they live.	N/A at this stage	N/A at this stage

5.12 Consider others who face health inequalities, such as: • Looked after and accommodated children and young people • Carers: paid/unpaid, family members • People who are homeless or those who experience homelessness: people on the street; those staying temporarily with friends/family; those in hostels/B&Bs • People involved in the criminal justice system: offenders in prison or on probation, ex-offenders • People with addictions and substance misuse problems • People who have poor literacy • People living in remote, rural and island locations	We do not expect a potential negative, or unequal, impact on people who face health inequalities.	N/A at this stage	N/A at this stage
5.13 Consider any other groups and risk factors relevant to this project.	None identified	N/A	N/A

6. HIA – How will the project impact on the health and wellbeing of people in Wales and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people, and the impact on the population in Wales.

How will the project impact on, or affect:	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Actions taken (and who by)
6.1 People being able to access the service offered.	We do not expect a potential negative, or unequal, impact on people's ability to access the service offered.	N/A	N/A
6.2 People being able to improve or maintain healthy lifestyles.	We do not expect a potential negative, or unequal, impact on people's ability to improve or maintain healthy lifestyles.	N/A	N/A
6.3 People in terms of their income and employment status.	We do not expect a potential negative, or unequal, impact on people in terms of their income and employment status.	N/A	N/A
6.4 People in terms of their use of the physical environment.	We do not expect a potential negative, or unequal, impact on people's use of the physical environment.	N/A	N/A
6.5 People in terms of social and community influences on their health.	We do not expect a potential negative, or unequal, impact on people in terms of social and community influences on their health.	N/A	N/A
6.6 People in terms of macro-economic, environmental and sustainability factors.	We do not expect a potential negative, or unequal, impact on people in terms of macroeconomic, environmental and sustainability factors.	N/A	N/A

7. Please fill in section 7.1 after completing the EqHIA, and fill in the action plan.

7.1 Please summarize the potential positive and/or negative impacts of the project.	No specific equality impacts were identified.

Action plan for mitigation or improvement and implementation

	Action	Lead(s)	Timescale	Actions taken *(state who by)*
7.2 What are the key actions identified as a result of completing the EqHIA?	None at this stage	N/A	N/A	N/A
7.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed?	No	N/A	N/A	N/A
7.4 What are the next steps?	Continues unchanged	N/A	N/A	N/A
7.5 Review of project and EqHIA	Review guidance in 3 years	AWTTC	[TBC]	N/A

AWTTC's EqHIA template is adapted from the Cardiff & Vale University Health Board EHIA template.