NHS
Cheshire and Merseyside

Cheshire and Merseyside (C&M) Integrated Care Board (ICB) Chronic Obstructive Pulmonary Disease (COPD) Biologic Therapy Standard Operating Procedure (SOP)

Organisations	Cheshire and Merseyside Integrated Care Board in collaboration with all Secondary Care Providers and relevant tertiary care and community providers across the ICB including: Mid Cheshire FT, Liverpool University Hospital FT, Liverpool Heart and Chest Hospital, Mersey West Lancs FT, North Cheshire and Mersey FT, East Cheshire FT, Wirral University FT, Countess of Chester FT, Merseycare, CWP
Implementation date	21st September 2026
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Approval	C&M Respiratory Board – 24 September 2026
Collaborators in the development of the SOP	Consultant Respiratory Physicians representing all hospitals in C&M Community Respiratory team members Respiratory Specialist Nurses Respiratory Specialist Pharmacists Respiratory Specialist Physiotherapists Hospital Pharmacists Hospital Respiratory Service Managers ICB Medicines Management team ICB Medicines High Cost Drugs team Primary Care representatives ICB Senior Commissioning Manager NHSE Northwest Coast Respiratory Network team Health Innovation Northwest Coast

1. Introduction

Biologics offer a new treatment for chronic obstructive pulmonary disease (COPD) patients with frequent exacerbations, elevated eosinophil counts, and ongoing symptoms despite optimised care. A 30% reduction in exacerbation frequency is expected in patients initiated on COPD Biologic therapy, leading to an improved health related quality of life, improved health and a longer life expectancy.

COPD is 1 of the 5 priority areas (for adults) in the Core20PLUS5 approach. There are strong links between deprivation and increased emergency healthcare use and costs. Reducing health inequalities is embedded in this SOP.

With dupilumab receiving a positive NICE recommendation (Overview | Dupilumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils | Guidance | NICE) in March 2026 and Mepolizumab receiving positive NICE recommendation (Overview | Mepolizumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils | Guidance | NICE) in June 2026 , we can reduce exacerbation-related harm and improve COPD outcomes.

2. Purpose

The purpose of this SOP is to define the safe, effective, equitable and appropriate use of biologic therapies as add on maintenance treatment for adults with uncontrolled COPD and raised blood eosinophil counts in Cheshire and Merseyside.
This SOP ensures that COPD biologics are prescribed:

- only for patients who meet NICE eligibility criteria (and are monitored in line with NICE mandated stopping rules)
- are initiated following MDT approval once patients are optimised in line with ‘Cheshire and Merseyside Fundamentals of COPD Care’
- in line with the agreed roll out plan aimed at reducing health inequalities

The adoption of this SOP is expected to move the healthcare utilisation and financial cost of COPD management from reactive non-elective secondary care admissions to an emphasis upon both proactive and preventative management.

3. Scope

Patient Eligibility:

Inclusion Criteria:

- Patients who meet NICE Criteria for COPD Biologic therapy
- Patients who have received the 'Cheshire and Merseyside Fundamentals of COPD Care'
- Aged 18 or over
- Registered with a GP practice in Cheshire and Merseyside

Exclusion criteria:

- Patients who are not compliant with evidence-based treatments
- Patients who are at the end of life (Patients with Advanced COPD who may be in the last years of life are not automatically excluded)
- Patients not registered with a GP practice in Cheshire and Merseyside

NICE Criteria for initiation of COPD Biologic therapy:

- Confirmed diagnosis of COPD
- Eosinophil count >0.29 x10^9 cells/L
- Inhaled ICS/LAMA/LABA for >12 months (or LABA/LAMA if ICS not appropriate)
- At least 1 Severe or 2 Moderate exacerbations of COPD in the last 12 months

Cheshire and Merseyside Fundamentals of COPD Care

- Care options for patients who currently smoke tobacco –
  - Actively engaged with Tobacco Dependency Treatment Service (TDTS)
  - Recent referral made to TDTS
  - Unable to stop
  - Unwilling to stop
- Recommend appropriate respiratory vaccinations:
  - Influenza in the last two years
  - Pneumococcal (ever)
  - Covid vaccinations up to date
  - RSV (ever)
  - Provide counselling to unvaccinated patients on importance of vaccination compliance
  - Unwilling to receive vaccinations despite counselling
- Pulmonary Rehabilitation
  - course completed
  - unsuitable
  - undergoing assessment/course
  - declined despite counselling on effectiveness

- Written personalised self-management plan including how to access Community COPD/Respiratory admission avoidance services either in place or not
- Co-morbidities optimised
- Inhaler technique assessed and optimised with confirmed adherence to treatment (> 75% in last 12 months)
- Referral to Energy Project Plus if living in a damp or cold home

4. Roles and Responsibilities

Consultant Respiratory Physicians
Provide clinical oversight and specialist support to the multi-professional team managing patients with COPD. This includes; assessment of patients prior to the initiation of COPD Biologic therapy if required, MDT meeting discussion about COPD Biologic suitability, assessment of overall treatment response and decisions regarding continuation or discontinuation of biologic therapy. Initiation and review of biologic therapy and prescription of Biologic treatment

Clinical leadership of COPD services and driving quality improvement across the system in partnership with multi-professional stakeholders.

Respiratory Specialist Clinicians including; Nurses, Physiotherapists, Advanced Practitioners, Pharmacists and Physician Associates (Hospital or Community Service)

Undertake comprehensive clinical assessments, confirm eligibility in line with NICE criteria and C&M Fundamentals of COPD care, provide patient education and ongoing support, coordinate monitoring and follow-up, present cases to MDT

Non-medical prescribers may arrange initiation and review of biologic therapy and prescribe treatment as part of a Consultant Respiratory Physician led service.

Review patients with a COPD exacerbation being treated in Hospital, Hospital at home or Virtual Ward services to optimise care, whilst an inpatient and/or following discharge.

Invite patients to a comprehensive COPD review in line with the ICB wide approach to pro-actively identify patients eligible for COPD Biologic therapy.

Community COPD/Respiratory admission avoidance services

Provide exacerbation support for patients with COPD Flare ups who are taking COPD Biologic therapy. Input into the MDT discussion about patient selection for treatment.

Hospital Pharmacy teams

Provide medicines governance oversight, including formulary assurance and compliance with local and national prescribing requirements.

Homecare Provider

Supply biologic medication, provide injection training, and support adherence in line with agreed homecare arrangements.

<u>System responsibilities</u>

Role of Primary Care

- Ensure accurate diagnosis of COPD with quality assured diagnostic spirometry
- Provide an annual COPD review
- Optimise inhaled therapy
- Deliver the Cheshire and Merseyside Fundamentals of COPD Care in line with current best practice
- Identify and treat co-morbidities
- Identify frequent exacerbators and provide patients with a written self-management plan including Community COPD/Respiratory admission avoidance services self-referral
- Share patient data via Cipha with clinical teams to allow proactive and efficient care of patients with COPD

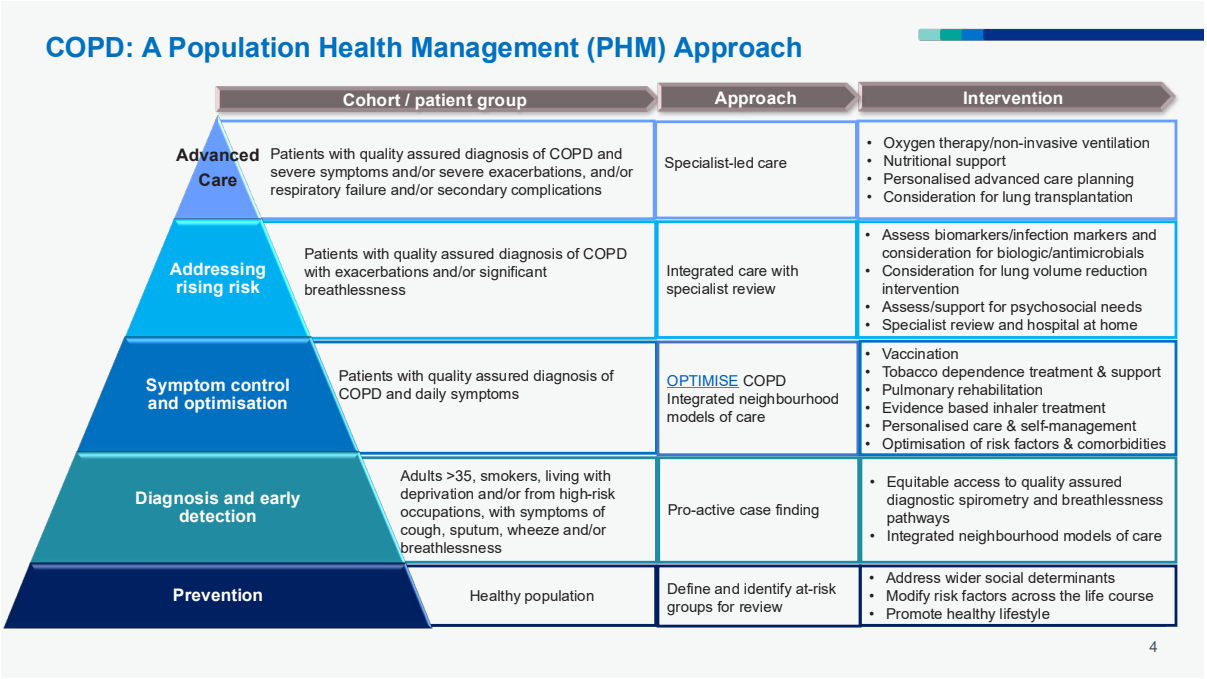
Role of Community and Hospital based Respiratory Specialist Care:

- Pro-actively identify patients who may be suitable for COPD Biologic therapy based upon NICE criteria
- Face to face review by a Respiratory Specialist (Experienced healthcare professional with appropriate training)
- COPD MDT discussion regarding Biologic therapy initiation (This MDT must contain a Consultant Respiratory Physician)
- Completion of the C&M COPD Biologic therapy MDT referral form and COPD Biologic therapy MDT Outcome form
- Completion of Blueteq form
- Prescription of Biologic therapy via Homecare services
- On-going follow up and review of patients treated with COPD Biologic therapy (This can be face to face, phone or digital follow up)
    - 3-6 months after initiation
    - 12 months after initiation
    - Every 12 months beyond first year
- On-going prescription of Biologic therapy via Homecare services

Service configuration of specialist respiratory services should be determined at each site based upon existing service configuration and capacity to review patients.

5. Service Configuration

The Cheshire and Merseyside COPD Biologic service model covers all elements of healthcare using a population health management approach.



The COPD Biologic therapy service will be provided as a partnership model, delivered by Consultant Respiratory Physician and Hospital pharmacy team in partnership with an Integrated Respiratory Team and the wider COPD MDT.

Proactive identification of patients suitable for Biologic therapy is key to reducing health inequalities. An ICB wide approach to pro-actively identify patients eligible for COPD Biologic therapy will be adopted. Mechanisms to identify suitable patients:

- Optimisation and COPD biologic assessment of all patients admitted to hospital, hospital at home or Virtual Ward services
- Integrated, cross system working to diagnose COPD early and fully optimise patients in their Primary care setting
- Proactive identification of patients in primary care who are fully optimised and continue to have 2 or more moderate exacerbations of COPD/year

Cheshire and Merseyside proactive identification roll out plan aimed at reducing health inequalities:

Priority group 1: Patients with a Severe Exacerbation (Exacerbation treatment in Hospital, Hospital at home or Virtual Ward)

Priority group 2: Patients with recurrent exacerbations accessing Community COPD/Respiratory admission avoidance services

Priority group 3: IMD Quintile 1 with >1 COPD exacerbations/year

Priority group 4: IMD Quintile 2 with >1 COPD exacerbations/year
Priority group 5: All patients with >1 COPD exacerbations/year not included in groups 1-4

Patients who are suitable and eligible for COPD Biologic therapy and present via an alternative route can be started on treatment following MDT assessment and discussion. Referrals from Primary care teams for consideration of COPD Biologic therapy should be made via existing referral routes for COPD specialist opinion.

COPD Biologic therapy service configuration overview

COPD Biologic service	Hospital Trust and site	Community Respiratory Team	Projected % of patients in C&M suitable for COPD Biologics
Liverpool	LUHG – The Royal Liverpool	LUHG	26
Knowsley	LUHG - LHCH	LUHG - LHCH	8
South Sefton	LUHG - Aintree	Merseycare	7
St Helens	MWL- Whiston	MWL	9
Southport & Formby	MWL – Southport	Merseycare	5
Mid Cheshire	Mid Cheshire Hospital	CCICP	9
Countess West Cheshire	Countess of Chester Hospital	CWP	8
Macclesfield East Cheshire	Macclesfield Hospital	Macclesfield Hospital	3
Wirral	WUTH	WUTH	14
Warrington & Halton	NCM	NCM	11

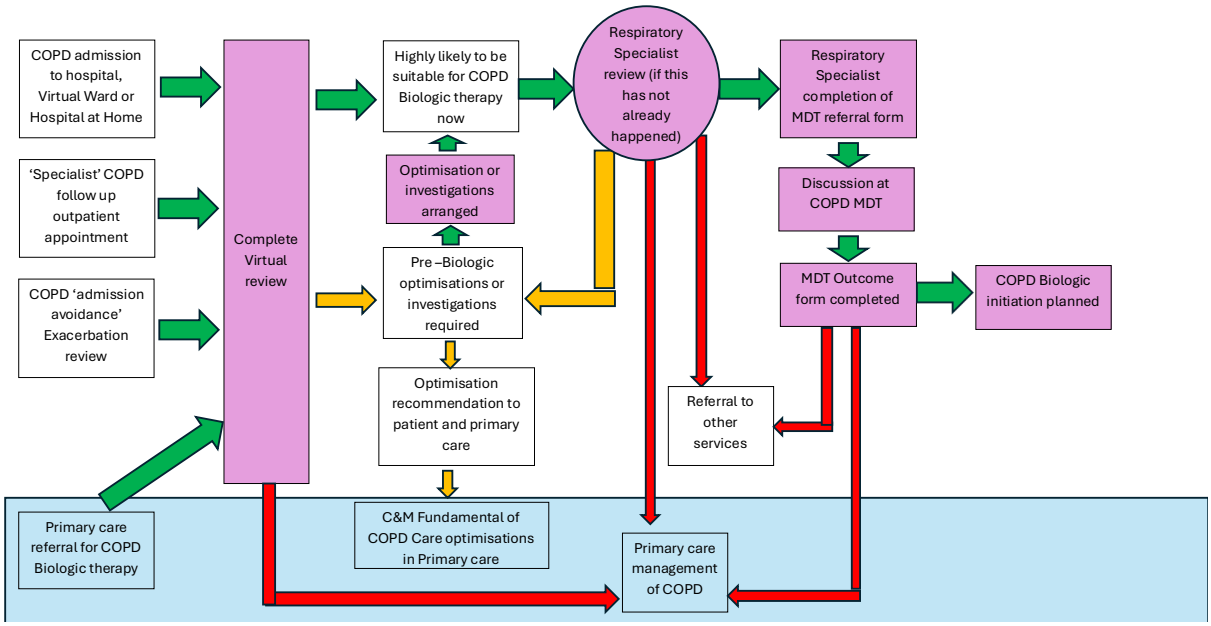
Full details of COPD Biologic therapy service configuration:

C&M%20COPD%20Biologic%20Service9

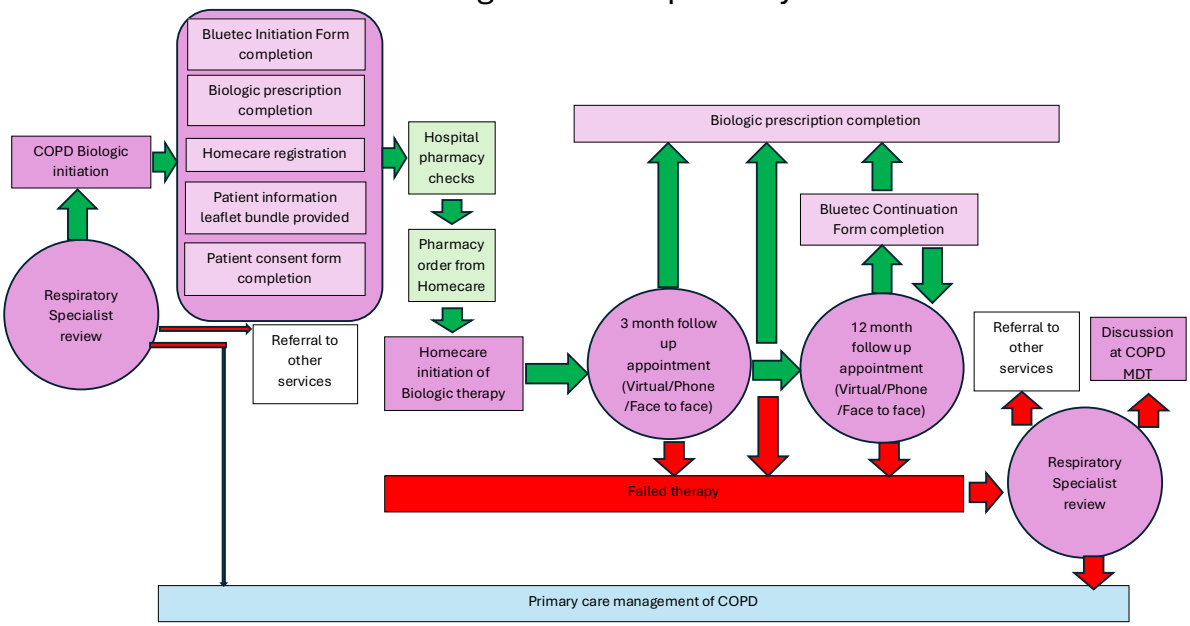
6. Clinical Procedures

Each COPD Biologic team will be an integrated partnership between a Consultant Respiratory Physician, a hospital-based pharmacy team, a community respiratory team and primary care. All teams will follow the same clinical pathway, with the delivery model dependent upon existing workforce.

COPD Biologic referral pathway

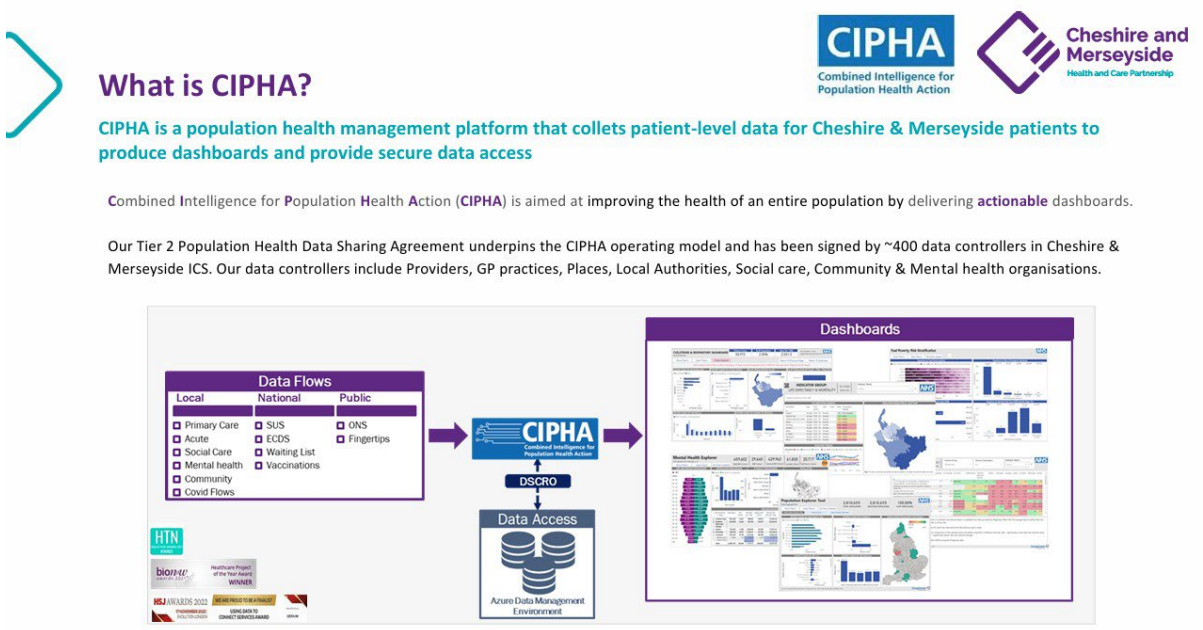


COPD Biologic initiation pathway



*See appendices for C&M wide documentation

A bespoke tool has been developed by Graphnet using the Fuel Poverty and Respiratory Dashboard within the Combined Intelligence for Population Health Action (CIPHA) platform. This has been developed in partnership with Respiratory specialists to identify patients who meet the NICE eligibility for COPD Biologics. Following approval by the C&M ICB Data Access and Assets Group, proactive identification of patients in priority groups 1-5 will be made via this tool, with access restricted to patients within the clinicians local catchment area. Clinicians will only be able to access those patients information who have given consent to their data being shared from their practice.
Patients who have opted out of data sharing remain eligible to be referred to COPD Biologic services. Depending upon the 'opt out' conditions, patients may not benefit from proactive case-finding activity. Patient consent will be required for their GP to provide relevant clinical information to their Respiratory team as part of their COPD Biologic therapy suitability assessment.



Specialist teams will identify patients who meet NICE criteria for COPD Biologic therapy. Patients will be invited to an appointment for full optimisation and assessment for treatment.

All patients being assessed within a COPD Biologic service will be offered the opportunity to take part in approved research studies and audit evaluation of the roll out of the C&M Biologic service.

COPD Biologic therapy assessment:

All patients must have at least one face to face assessment in a COPD Biologic therapy clinic prior to initiation of Biologic therapy and must have a named Consultant Respiratory Physician responsible for their treatment, who they have met. Many patients will require at least two face-to-face appointments as part of the COPD Biologic therapy assessment and initiation pathway.

All patients require the following prior to referral to the COPD Biologic MDT decision making meeting:

1) A structured baseline assessment, including:
   - Medical history and comorbidities
   - Medications and allergies
   - Respiratory symptom assessment, including:
     - MRC Dyspnoea score
     - CAT score
     - Chronic bronchitis symptoms
   - Detailed exacerbation history for the preceding 12 months
   - Respiratory failure history
   - Smoking status recorded
   - Pulmonary rehabilitation status recorded

2) Clinical interventions:
   - Review of inhaler technique and adjustment if required
   - Review of inhaler adherence (In last 12 months >75% prescription requests)
   - Tobacco dependency treatment counselling and referral for current smokers
   - Vaccinations recommended and (influenza, pneumococcal, RSV and COVID). counselling provided on the importance of vaccination if not fully vaccinated
   - Counselling on benefits of Pulmonary rehabilitation, and a referral to PR if this has not already been completed and there are no contraindications
   - Personalised self-management plan which includes details on how to self-refer to the local Community Respiratory service for exacerbation assessment and management
   - Referral to Energy Project Plus if the patient live in a cold or damp home Health Innovation North West Coast - Fuel poverty toolkit
   - Optimisation of treatment for comorbidities

3) Mandatory Pre-COPD Biologic tests:
   - Post bronchodilator spirometry (unless the patient has a absolute contraindication or is physically unable to carry out the test)
   - Blood eosinophil counts - highest in last 12 months and highest recorded
   - Current BMI
   - Oxygen saturations at rest (air or on usual LTOT oxygen prescription)

Other pre-initiation tests and assessments should be considered:
   - FeNO
   - 6 minute walk test
   - Sputum sample for general bacteriology
   - Sputum sample for TB/NTM
   - CT scan of the Thorax
   - Rockwood Frailty score
   - Gold Standards Framework (GSF) register suitability assessment and status
   - PHQ–9
   - GAD-7
   - NT Pro BNP +/- Echocardiogram
   - ECG

Following assessment by a Respiratory Specialist, if Biologic therapy is being considered, the C&M Site specific **COPD Biologic referral form** should be completed. (This will need to be completed after the COPD Biologic therapy assessment clinic)

Patients with a completed COPD Biologic referral form should be discussed in a COPD Biologic MDT meeting and a **COPD Biologic MDT Decision form** should be completed.

COPD Biologic therapy initiation:

If initiation of COPD Biologic therapy is agreed at the COPD Biologic MDT meeting, the patient should attend a face to face meeting with a Respiratory Specialist to be counselled on COPD Biologic therapy. Processes should be completed in each organisation in line with their own hospital's policies and procedures regarding initiation of patients on Homecare therapy. In addition, a **Blueteq initiation form** should be completed for all patients starting COPD Biologic therapy.

COPD Biologic therapy follow up and monitoring:

The responsibility for the on-going prescribing and follow up of COPD care for patients initiated on COPD Biologic therapy remains with the initiating COPD Biologic team unless the patient moves out of the area and their care is handed over to another team.

In the event of a suspected COPD exacerbation, all patients are required to self-refer to their local community respiratory service for exacerbation assessment and management, or out of hours contact 111.

All patients should be provided with contact details of who to call (or e-mail) if they are experiencing potential side effects or wish to stop their Biologic therapy for another reason.

In the first year of treatment, all patients require a 3-6 month review to assess treatment adherence, tolerance and efficacy. Ad hoc reviews may also be needed if treatment failure or discontinuation is being considered. A **COPD Biologic therapy review form** should be completed at all reviews.

At the end of the first year of therapy and annually thereafter, an annual assessment should take place to assess treatment adherence, tolerance and efficacy. A **COPD Biologic therapy review form** should be completed at this review.

- If the patient is continuing with the same COPD Biologic therapy, a **Blueteq continuation form** should also be completed.
- If the patients does not meet NICE criteria for continuation of their COPD Biologic therapy or they need to discontinue for another reason, they may be considered for an alternative COPD Biologic therapy via the COPD Biologic MDT meeting.

Please see appendices for the form details

Annual review NICE Criteria for continuation of COPD Biologic therapy:
When compared with the 12 months prior to starting COPD Biologic therapy, the number of severe exacerbations of COPD in the last 12 months is lower
OR
When compared with the 12 months prior to starting COPD Biologic therapy, the number of severe exacerbations of COPD in the last 12 months is the same and the number of moderate exacerbations is lower.

7. Related Policies and References

https://www.england.nhs.uk/long-read/copd-commissioning-strategies-resources/

https://www.england.nhs.uk/long-read/business-case-guidance-copd-biologics/#8-appendix-a-model-pathway

History | Dupilumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils | Guidance | NICE

Overview | Mepolizumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils | Guidance | NICE

10 Year Health Plan for England: fit for the future - GOV.UK

8. Appendices

COPD Biologic MDT Referral v1 – Copy form

COPD Biologic MDT Decision Form v1 – Copy form

COPD Biologic therapy review v1 – Copy form

Blueteq forms:

Dupilumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils (TA1142) - Auto-approval initiation V1

Please indicate whether patient meets the following NICE criteria:	Please tick
1. I confirm the dose is 300mg given every other week	○ Yes ○ No * Required
2. I confirm the patient is an adult with uncontrolled chronic obstructive pulmonary disease (COPD) and with raised blood eosinophils **Uncontrolled COPD is defined as 1 or more severe exacerbations or 2 or more moderate exacerbations in the previous 12 months. Raised blood eosinophils is defined as a blood eosinophil count of 0.3 x 10^9 cells per litre or more (300 cells per microlitre or more).**	○ Yes ○ No * Required
3. I confirm Dupilumab will be used as an add-on maintenance treatment option	○ Yes ○ No * Required
4. I confirm the patient is having the following: Triple therapy including an inhaled corticosteroid, a long-acting beta2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA) **OR** Double therapy including a LABA and a LAMA if inhaled corticosteroids are not appropriate.	○ Yes ○ No * Required
5. Reimbursement of the drug will be no greater than agreed in the commercial arrangement	

Dupilumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils (TA1142) - Auto-approval continuation V1

Continuation Form Section:	
Please indicate whether patient meets the following NICE criteria:	**Please tick**
1. I confirm the dose is 300mg given every other week	○ Yes ○ No * Required
2. I confirm dupilumab response has been assessed at 12 months and compared with the 12 months before starting it, the number of severe exacerbations: is lower **OR** is the same, and the number of moderate exacerbations is lower	○ Yes ○ No * Required
3. Reimbursement of the drug will be no greater than agreed in the commercial arrangement	

Mepolizumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils (TA1166) - Auto-approval initiation V1

Please indicate whether patient meets the following NICE criteria:	Please tick
1. I confirm the dose is 100mg given every four weeks	○ Yes ○ No * Required
2. I confirm the patient is an adult with uncontrolled chronic obstructive pulmonary disease (COPD) and with raised blood eosinophils **Uncontrolled COPD is defined as 1 or more severe exacerbations or 2 or more moderate exacerbations in the previous 12 months. Raised blood eosinophils is defined as a blood eosinophil count of 0.3 x 10^9 cells per litre or more (300 cells per microlitre or more).**	○ Yes ○ No * Required
3. I confirm mepolizumab will be used as an add-on maintenance treatment option	○ Yes ○ No * Required
4. I confirm the patient is having triple therapy including an inhaled corticosteroid, a long-acting beta2- agonist (LABA) and a long-acting muscarinic antagonist (LAMA)	○ Yes ○ No * Required
5. Reimbursement of the drug will be no greater than agreed in the commercial arrangement	

Mepolizumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils (TA1166) - Auto-approval continuation V1

Continuation Form Section:	
Please indicate whether patient meets the following NICE criteria:	**Please tick**
1. I confirm the dose is 100mg given every four weeks	○ Yes ○ No * Required
2. I confirm mepolizumab response has been assessed at 12 months and compared with the 12 months before starting it, the number of severe exacerbations: is lower **OR** is the same, and the number of moderate exacerbations is lower	○ Yes ○ No * Required
3. Reimbursement of the drug will be no greater than agreed in the commercial arrangement	

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IAPT Questionnaire 1
PHQ-9

Over the last 2 weeks, *on how many days* have you been bothered by any of the following problems?		Not at all	Several days	More than half the days	Nearly every day
1	Little interest or pleasure in doing things	0	1	2	3
2	Feeling down, depressed or hopeless	0	1	2	3
3	Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4	Feeling tired or having little energy	0	1	2	3
5	Poor appetite or overeating	0	1	2	3
6	Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7	Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8	Moving or speaking so slowly that other people could have noticed, or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9	Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

A11 – PHQ-9 Total Score ☐

IAPT Questionnaire 2
GAD-7

Wk….. Date……..

Over the last 2 weeks, *on how many days* have you been bothered by any of the following problems?		Not at all	Several days	More than half the days	Nearly every day
1	Feeling nervous, anxious or on edge	0	1	2	3
2	Not being able to stop or control worrying	0	1	2	3
3	Worrying too much about different things	0	1	2	3
4	Trouble relaxing	0	1	2	3
5	Being so restless it is hard to sit still	0	1	2	3
6	Becoming easily annoyed or irritable	0	1	2	3
7	Feeling afraid as if something awful might happen	0	1	2	3

A12 – GAD-7 Total Score ☐