Annex 5b
COPD - Care Contents
Pursuant to Annex 11 Items 1 to 3 of the
Risk Structure Compensation Ordinance [RSAV]
Requirements To Be Met by Disease Management Programmes for Patients with Chronic Obstructive Airway Diseases

Part II: Chronic obstructive pulmonary disease (COPD)

1. Treatment according to the current state of medical science taking account of evidence-based guidelines or in accordance with the best available evidence as well as giving due consideration to the care provision sector concerned (Sect. 137f Para. 2 Sent. 2 No. 1 of the Fifth Book of the German Social Security Code [Sozialgesetzbuch])

1.1 Definition of chronic obstructive pulmonary disease (COPD)

COPD is a chronic, usually progressive airway and pulmonary disease which is characterised by an airway obstruction that is not completely reversible by administration of bronchodilators and/or glucocorticosteroids and is based on chronic bronchitis with or without pulmonary emphysema. Chronic bronchitis is characterised by continuous coughing, usually with phlegm being brought up, over a period of at least one year. Chronic obstructive bronchitis is additionally characterised by a permanent airway obstruction with or without pulmonary overinflation. A pulmonary emphysema is characterised by a decrease in pulmonary gas exchange area. Obstruction, pulmonary overinflation and impaired gas exchange may vary in terms of extent, irrespectively of each other.

1.2 Adequate diagnostics for enrolment in the COPD Disease Management Programme

Diagnostics of COPD is based on a case history typical of the disease, the existence of characteristic symptoms (possibly) and the evidence of an airway obstruction without or with poor reversibility.

1.2.1 Case history, symptoms and physical examination

In terms of case history, the following factors require particular consideration:
– daily bouts of coughing, mostly with phlegm being brought up on a daily basis, over a period of at least one year,
– breathing difficulties as a result of strenuous physical exercise or even when resting in the case of severe forms of the disease,
– smoking with inhalation of smoke over many years,
– occupational history,
– history of infections,
– relevant disorders in differential diagnostic terms, particularly bronchial asthma and heart disorders.

The aim of the physical examination is to identify signs of bronchial obstruction, pulmonary overinflation and pulmonary heart disease. Findings may be negative in patients affected by a mild form of COPD. In severe cases of COPD, rhonchus and dry rale may be absent with breath sounds being significantly diminished.
Besides COPD, patients may simultaneously suffer from bronchial asthma. In such cases, there will also be signs of bronchial hyperreactivity and a greater variability and/or reversibility of the airway obstruction.

1.2.2 Multi-stage pulmonary function diagnostics

Basic diagnostics encompass the measurement of the airway obstruction with evidence of absent or poor reversibility. Pulmonary function diagnostics serve to confirm diagnosis, to allow differentiation from other obstructive airway and pulmonary disorders as well as to follow up the development and therapy of the disease.

As far as a diagnosis in respect of enrolment is concerned, the existence of a COPD-typical case history, evidence of FEV\textsubscript{1} reduction to below 80% of the desired level and compliance with at least one of the following criteria are required:

- evidence of obstruction with FEV\textsubscript{1}/VC ≤ 70% and increase of FEV\textsubscript{1} by less than 15% and/or by less than 200 ml 10 minutes after inhalation of a short-acting beta-2 sympathomimetic or 30 minutes after inhalation of a short-acting anticholinergic (bronchodilator reversibility test),

- evidence of obstruction with FEV\textsubscript{1}/VC ≤ 70% and increase of FEV\textsubscript{1} by less than 15% and/or by less than 200 ml after administration of systemic glucocorticosteroids for at least 14 days or administration of inhaled glucocorticosteroids for at least 28 days in a stable phase of the disease (glucocorticosteroid reversibility test),

- evidence of an increase in airway resistance or of pulmonary overinflation or impaired gas exchange in patients with FEV\textsubscript{1}/VC > 70% and of a radiologic examination of the thoracic organs which has shown there is no other disease causing the symptoms.

Simultaneous enrolment in Part I (bronchial asthma) and Part II (COPD) of the Disease Management Programme is not possible. For details of further enrolment criteria in respect of Disease Management Programmes please refer to Item 3. The doctor should check whether the patient would benefit from enrolment in view of the therapy objectives mentioned under Item 1.3 and be able to assist with their realisation.

1.3 Therapy objectives

The therapy serves to enhance life expectancy as well as maintain and improve the quality of life affected by COPD, whereby the aim should be to meet the following therapy objectives based on the given patient’s age and associated disorders:

1. Avoidance/Reduction of:
   - acute and chronic disease-related impairments (e.g. exacerbations, associated and secondary disorders),
   - disease-related impairments in everyday physical and social activities,
   - quick progression of the disease
while trying to achieve the best possible pulmonary function and minimising undesirable effects of the therapy.
2. Reduction of COPD-related mortality.

1.4 Differentiated therapy planning

Differentiated therapy planning should be undertaken together with the given patient on the basis of an individual risk assessment, whereby the existence of mixed forms (bronchial asthma and COPD) should also be given due consideration. The care provider should examine whether the patient would benefit from a specific form of intervention in view of the therapy objectives mentioned under Item 1.3. The execution of diagnostic and therapeutic measures should be coordinated with the patient following detailed clarification in terms of the benefits and risks involved. Based on the individual risk assessment and the general therapy objectives, individual therapy objectives should be set together with the patient. For individual risk assessment purposes, the given patient’s pulmonary function (FEV$_1$) and his or her body weight are particularly relevant in terms of prognosis.

1.5 Therapeutic measures

1.5.1 Non-medicinal measures

1.5.1.1 General non-medicinal measures

The doctor treating the given patient should draw the latter’s attention above all to the following:

- COPD noxae and/or COPD-triggering factors (e.g. active and passive smoking, extreme (also vocation-related) exposure to dust) and their avoidance,
- prevention of infections,
- medicines (above all self-medication) which may result in an aggravation of COPD,
- an adequate diet (hypercaloric) in the case of underweight $^1$, $^2$, $^3$.

1.5.1.2 Smoking cessation

Smoking with inhalation of smoke makes COPD significantly more difficult to treat, which is why the focus of the given therapy should be on quitting smoking.

Within the framework of the given therapy, the doctor treating the patient concerned should point out the specific risks patients with COPD subject themselves to by

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smoking while, at the same time, linking this into specific counseling strategies and urgently advising the patient concerned to quit smoking.

- The smoking status of each patient should be ascertained at each consultation.
- Smokers should be motivated in a clear, powerful and personal form to quit smoking.
- It should further be ascertained whether the given smoker is prepared to start an attempt to quit smoking at the given point in time.
- Smokers prepared to quit smoking should be given access to professional advisory assistance (e.g. of a behavioural therapeutic form).
- Follow-up appointments should be arranged, if possible in the first week following the date on which the patient quitted smoking.

1.5.1.3 Physical training

Physical training usually results in a reduction of COPD-related symptoms and an enhancement of exercise tolerance and may improve the quality of life or reduce morbidity. That is why the doctor treating the given patient should motivate the patient concerned on a regular basis to engage in appropriate physical training measures. Regular training on at least one occasion per week should be recommended. The nature and scope of the physical training measures should take into account the severity of the given patient’s disorder and the availability of suitable measures.

1.5.1.4 Training and Disease Management Programmes

Any patient with COPD should be given access to a structured, evaluated, target group-specific and publicised Training and Disease Management Programme. Apart from that, the enrolment and quality assurance criteria mentioned under Item 4.2 are applicable.

1.5.1.5 General physiotherapy (respiratory therapy)

General physiotherapy with a focus on respiratory therapy is a supplementary constituent part of the non-medicinal treatment of COPD.

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In appropriate cases (e.g., high level of phlegm retention), the doctor can therefore give due consideration to prescribing respiratory therapy/physiotherapy in accordance with the Regulations Governing the Prescription of Remedies [Heilmittelrichtlinien].

1.5.2 Long-term oxygen therapy

If there is evidence of severe chronic hypoxaemia, the doctor should check whether a long-term oxygen therapy is indicated.

1.5.3 Home ventilation

In the case of chronic hypercapnia, intermittent non-invasive home ventilation may be taken into consideration.

1.5.4 Rehabilitation

Outpatient or inpatient pneumological rehabilitation is a process, whereby patients suffering from COPD are given support by a multi-disciplinary team, enabling them to achieve and maintain their best possible level of physical and psychical health, as well as to retain or restore their ability to work and play an active role in society in an autonomous, equal manner. The aim of rehabilitation

services is to help avoid or counter any disadvantages caused by COPD and/or its associated and secondary disorders, whereby the special needs of children and juveniles affected by this disease should be given due consideration.

Rehabilitation can be a constituent component of the comprehensive care provided to patients with COPD with the aim of achieving long-term success.

The necessity of rehabilitation services provision should be examined on an individual basis in accordance with Item 1.6.4.

1.5.5 Surgical measures

In appropriate cases (above all in patients with large bullae and/or severe emphysema in the upper lung field), surgical measures improving pulmonary function should be given due consideration

1.5.6 Psychological, psychosomatic and psychosocial care

On account of the complex interaction between somatic, psychological and social factors affecting patients with COPD, the doctor should check to what extent the patient concerned would benefit from psychotherapeutic (e.g. behavioural therapeutic) and/or psychiatric measures. In the case of a psychological imbalance serious enough to be considered a disorder, the treatment should be supplied by qualified care providers.

1.5.7 Medicinal measures

For pharmacotherapy purposes, an individual therapy plan should be drawn up and self-management measures decided together with the given patient (see also structured training programmes (Item 4)).

Taking account of any counterindications and patient preferences, the primary aim is to use such medicines as have been proven safe and effective in respect of the therapy objectives mentioned under Item 1.3 in prospective, randomised, controlled trials. Preference should be given to such substances/substance groups or combinations as provide the greatest benefits in this respect.

In view of the fact that the response to medicines can vary from person to person as well as in time terms (e.g. theophylline, inhaled and oral glucocorticosteroids), due consideration should be given to carrying out an omission test (if appropriate) while closely monitoring the given patient’s symptoms and pulmonary function.

To the extent that substances or substance groups other than those mentioned in this Annex are to be prescribed within the framework of individual therapy planning,

the given patient is to be informed as to whether any evidence is available concerning the effectiveness of these substances or substance groups in respect of the therapy objectives mentioned under Item 1.3.

The aim of the medicinal therapy is above all to alleviate the symptoms (particularly coughing, phlegm retention and breathing difficulties) and treat exacerbations promptly while reducing the rate of their incidence.

As far as the medication of COPD is concerned, a distinction is made between as-needed medication (medicines administered as required in the case of, for example, physically stressful situations that can be anticipated or for treating dyspnoea) and regular medication (medicines administered regularly by way of basic therapy).

The substances or substance groups primarily to be used include:

As-needed therapy:
- short-acting beta-2 sympathomimetics (fenoterol, salbutamol, terbutalin),
- short-acting anticholinergics (ipratropiumbromide),
- combination of short-acting beta-2 sympathomimetics and anticholinergics.

In justified cases:
- theophylline (in a quick-release form),
- in the case of phlegm retention, consideration should be given to:
  - inhalation of salt solutions,
  - mucoactive substances.

For regular therapy purposes if necessary:
- long-acting anticholinergic (tiotropiumbromide),
- long-acting beta-2 sympathomimetics (formoterol, salmeterol).

In justified cases:
- theophylline (in a delayed-release form),
- inhaled glucocorticosteroids
  25) (for moderate and severe COPD, particularly if the patient concerned also shows signs of bronchial asthma),
- systemic glucocorticosteroids.

In the event of exacerbations occurring frequently, the use of mucoactive substances (acetylcysteine, ambroxol, carbocisteine) may be taken into consideration.

Following initial instruction in inhalation techniques, these should be monitored at least once in every documentation period.

1.5.7.1 Immunisations

Influenza and pneumonia immunisations should be given due consideration for patients with COPD according to the latest STIKO Recommendations.

1.5.7.2 Respiratory infections

Infections often result in an acute deterioration of the disease. In such cases, the prime need is to intensify the level of the as-needed therapy, in particular through the short-term administration of systemic glucocorticosteroids. Should any signs of

bacterial infection (e.g. yellow-green sputum) be identified, consideration should be given to executing antibiotic treatment at an early stage 27).

1.6  Cooperation of the various care provision sectors

The treatment of patients with COPD necessitates cooperation between all the sectors (outpatient, inpatient) and facilities concerned. Appropriately qualified treatment must be guaranteed along the entire care provision chain.

1.6.1  Coordinating doctor

The long-term treatment of a given patient and the associated documentation work required under the Disease Management Programme must be carried out by the patient’s family doctor (general practitioner) within the scope of his or her duties set out and described in Sect. 73 of the Fifth Book of the German Social Security Code [Sozialgesetzbuch].

In exceptional cases, a patient with COPD can choose to have the long-term treatment, documentation work and coordination of further activities within the framework of the Disease Management Programme carried out by an appropriately qualified specialist who is licensed or authorised to provide these services or by an appropriately qualified facility that is licensed or authorised to provide these services or is participating in the provision of outpatient medical care in accordance with Sect. 116b of the Fifth Book of the German Social Security Code [Sozialgesetzbuch]. This applies above all in cases where the patient concerned has already been treated by the given doctor or facility on a long-term basis prior to enrolment in the Disease Management Programme or where care provision in this form is considered necessary for medical reasons. The referral regulations set out under Item 1.6.2 require due consideration on the part of the doctor or facility chosen if their specific qualifications are insufficient for treating the patients for the referral reasons mentioned therein.

In the case of such patients as are subject to ongoing treatment by a specialist doctor or facility, the specialist or facility concerned should examine whether the given patient can be referred back to his or her family doctor (general practitioner) in the event that the patient’s condition undergoes stabilisation.

1.6.2  Referral by the coordinating doctor to a specialist doctor or facility

The doctor should check whether patients should be referred to an appropriately qualified specialist or facility for additional treatment and/or enhanced diagnostics, in cases where above all the following indications/circumstances apply:

- if the therapy fails to be successful despite intensified treatment,
- if regular treatment with oral steroids becomes necessary,
- following emergency treatment,

- associated disorders (e.g. severe bronchial asthma, symptomatic cardiac insufficiency, other chronic pulmonary disorders),
- suspected respiratory insufficiency (e.g. for checking whether long-term oxygen therapy and/or intermittent home ventilation is indicated)
- suspected occupational COPD.

In all other cases the doctor should decide, according to his or her best judgment, whether a referral is necessary.

1.6.3 Admission to hospital

Indications requiring patients to undergo inpatient treatment include above all the following:
- suspected life-threatening exacerbation,
- serious, persistent or progressive deterioration despite initial treatment,
- suspected serious pulmonary infections,
- preparation for intermittent home ventilation.

Apart from that, inpatient treatment should particularly be taken into consideration in the case of exceptional deterioration or new complications and secondary disorders (e.g. in the event of severe cardiac insufficiency or pathological fracture).

In all other cases the doctor should decide, according to his or her best judgment, whether admission to hospital is necessary.

1.6.4 Prescription of rehabilitation services

The provision of rehabilitation services should be given special consideration in the case of severe forms of COPD with relevant disease-related consequences despite the provision of adequate medical treatment and usage of all therapy options available, particularly in the case of difficult and unstable disease development with severe bronchial obstruction, extreme bronchial hyperreactivity, psychosocial stress and/or in the case of serious, medicine-related complications.

2. Quality assurance measures (Sect. 137f Para. 2 Sent. 2 No. 2 of the Fifth Book of the German Social Security Code [Sozialgesetzbuch])

The details under Item 2 of Annex 1 apply accordingly.

The aim is to develop, within the framework of integrated care programmes, a specific common quality assurance system for Disease Management Programmes in order to implement cross-sector quality assurance procedures. The parties responsible are to be involved in this on an equal basis. Until such time as a cross-

sector quality assurance system is introduced, the existing separate responsibilities and competencies will continue to apply in the case of Disease Management Programmes too.

3. Participation requirements and duration of participation of insured persons (Sect. 137f Para. 2 Sent. 2 No. 3 of the Fifth Book of the German Social Security Code [Sozialgesetzbuch])

The attending doctor should check whether a patient with a confirmed diagnosis of COPD would benefit from enrolment in respect of the therapy objectives mentioned under Item 1.3 and would be able to participate actively in their realisation.

3.1 General participation requirements

The details set out under Item 3.1 of Annex 1 apply accordingly.

3.2 Special participation requirements

As far as a diagnosis in respect of enrolment is concerned, the existence of a COPD-typical case history, evidence of FEV$_1$ reduction to below 80% of the desired level and compliance with at least one of the following criteria are required. Findings that are used as a basis for enrolment must date from within the past 12 months.

- Evidence of obstruction with FEV$_1$/VC $\leq$ 70% and increase of FEV$_1$ by less than 15% and/or by less than 200 ml 10 minutes after inhalation of a short-acting beta-2 sympathomimetic or 30 minutes after inhalation of a short-acting anticholinergic (bronchodilator reversibility test).

- Evidence of obstruction with FEV$_1$/VC $\leq$ 70% and increase of FEV$_1$ by less than 15% and/or by less than 200 ml after administration of systemic glucocorticosteroids for at least 14 days or administration of inhaled glucocorticosteroids for at least 28 days in a stable phase of the disease (glucocorticosteroid reversibility test).

- Evidence of an increase in airway resistance or of pulmonary overinflation or impaired gas exchange in patients with FEV$_1$/VC $> 70\%$ and of a radiologic examination of the thoracic organs which has shown there is no other disease causing the symptoms.

Insured persons below 18 years of age cannot be enrolled in Part II (COPD) of the Disease Management Programme.

Simultaneous enrolment in Part I (bronchial asthma) and Part II (COPD) of the Disease Management Programme is not possible.
4. **Training courses (Sect. 137f Para. 2 Sent. 2 No. 4 of the Fifth Book of the German Social Security Code [Sozialgesetzbuch])**

The health funds are to inform insured persons and care providers about the objectives and content of the Disease Management Programmes. To this end, the contractually agreed care objectives, cooperation and referral regulations, underlying care remits and valid therapy recommendations must also be presented in a transparent manner. The given health fund may appoint a third party to carry out this task.

4.1 **Training courses for care providers**

Training courses for care providers serve the purpose of helping to achieve the contractually agreed care objectives. The content of the training courses is tailored to cater for the agreed management components, above all with regard to cross-sector cooperation. The contracting parties are to define requirements to be met by the regular training of participating care providers relevant to the Disease Management Programmes concerned. They can make the long-term participation of care providers conditional upon the provision of appropriate attendance confirmations.

4.2 **Training courses for insured persons**

Any patient with COPD should be given access to a structured, evaluated, target group-specific and publicised Training and Disease Management Programme.

Training courses for patients serve the purpose of enabling the patient concerned to better manage the course of his or her disease and make informed decisions. To this end, a link should be established to the programme’s underlying structured medical content in accordance with Sect. 137f Para. 2 Sent. 2 No. 1 of the Fifth Book of the German Social Security Code [Sozialgesetzbuch]. The existing level of training of the insured person concerned should be given due consideration.

At the application stage, the training programmes to be applied must be notified to the German Federal Insurance Office and evidence provided of their focus on the therapy objectives mentioned under Item 1.3. Training and treatment programmes should take into account individual therapy plans. The appropriate qualifications of the care providers concerned are to be verified.

5. **Evaluation (Sect. 137f Para. 2 Sent. 2 No. 6 of the Fifth Book of the German Social Security Code [Sozialgesetzbuch])**

The details under Item 5 of Annex 1 apply accordingly.