Annex 9
(to Sects. 28b to 28g)

Requirements To Be Met by Disease Management Programmes for Patients with Chronic Obstructive Airway Diseases

Part I: Bronchial asthma

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 bronchial asthma

Bronchial asthma is a chronic inflammatory airway disease which is characterised by bronchial hyperreactivity and variable airway obstruction.

1.2 Diagnostics

Diagnostics of bronchial asthma is based on a case history typical of the disease, the existence of characteristic symptoms (possibly) and the evidence of a (partially) reversible airway obstruction and/or bronchial hyperreactivity.

1.2.1 Case history, symptoms and physical examination

In terms of case history, the following factors require particular consideration:
– repeated occurrence of attack-like, often nocturnal breathing difficulties and/or coughing with or without phlegm being brought up, above all in connection with allergenic exposure, during or after strenuous physical exercise, in connection with infections, thermal irritation, exposure to smoke and dust,
– seasonal variability of symptoms,
– positive family history (allergies, bronchial asthma),
– vocation-, activity- and environment-related triggering of breathing difficulties and/or coughing.

The aim of the physical examination is to identify signs of bronchial obstruction which, however, do not necessarily have to be present.

1.2.2 Multi-stage pulmonary function diagnostics

Basic diagnostics encompass measurement of airway obstruction and of its reversibility and variability. 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 \(^1\), \(^2\), \(^3\).

As far as a diagnosis in respect of enrolment is concerned, the existence of a current asthma-typical case history or one dating back no longer than twelve months in accordance with Item 1.2.1 and compliance with at least one of the following criteria are required:

In the case of adult patients, compliance with at least one of the following criteria is required:

- evidence of obstruction with \(\text{FEV}_1/\text{VC} \leq 70\%\) and evidence of (partial) reversibility through an increase of \(\text{FEV}_1\) by at least 15\% and at least 200 ml after inhalation of a short-acting beta-2 sympathomimetic,
- increase of \(\text{FEV}_1\) by at least 15\% and at least 200 ml after administration of systemic glucocorticosteroids for up to 14 days or administration of inhaled glucocorticosteroids for up to 28 days \(^2\), \(^4\),
- circadian PEF variability > 20\% for 3 to 14 days,
- evidence of bronchial hyperreactivity via a non-specific, standardised, multi-stage inhalational provocation test.

For patients aged between 5 and 17, compliance with at least one of the following criteria is required:

- evidence of obstruction with \(\text{FEV}_1/\text{VC} \leq 75\%\) and evidence of (partial) reversibility through an increase of \(\text{FEV}_1\) by at least 15\% after inhalation of a short-acting beta-2 sympathomimetic,
- increase of \(\text{FEV}_1\) by at least 15\% after administration of systemic glucocorticosteroids for up to 14 days or administration of inhaled glucocorticosteroids for up to 28 days \(^2\), \(^4\),
- circadian PEF variability > 20\% for 3 to 14 days,
- evidence of bronchial hyperreactivity via a non-specific, standardised, non-inhalational or via a non-specific, standardised, multi-stage inhalational provocation test.

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.

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1.2.3 Multi-stage allergologic diagnostics

In the case of suspected allergic origin of bronchial asthma, the doctor is to check whether multi-stage allergologic diagnostics should be performed.

Allergologic diagnostics should be performed and a therapy decision taken by
- a doctor specialising in allergology and having competence in pneumology or
- a doctor specialising in allergology and pneumology.

1.3 Therapy objectives

The therapy serves to enhance life expectancy as well as maintain and improve the quality of life affected by bronchial asthma, 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. symptoms, asthmatic attacks/exacerbations),
   - disease-related impairments in the physical, psychical and mental development of children/juveniles,
   - disease-related impairments in everyday physical and social activities,
   - progression of the disease,
   - undesirable effects of the therapy while trying to normalise or achieve the best possible pulmonary function and reduce bronchial hyperreactivity.

2. Reduction of asthma-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.
1.5 Therapeutic measures

1.5.1 Non-medicinal therapy and general measures

The doctor treating the given patient should draw the latter’s attention above all to the following:
– relevant allergens and their avoidance (as far as possible),
– other inhalation noxae and asthma-triggering factors (e.g. active and passive smoking, emotional stress) and their avoidance,
– medicines (above all self-medication) which may result in an aggravation of bronchial asthma.

1.5.2 Training and Disease Management Programmes

Any patient with bronchial asthma 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.

1.5.3 Physical training

Physical training may contribute to a reduction in asthma-related symptoms and an improvement of exercise tolerance and quality of life. That is why the doctor treating the given patient should regularly motivate the patient concerned to take responsibility for engaging in suitable physical training measures. The nature and scope of the physical training measures concerned should be checked once a year. Particularly in the case of school children with bronchial asthma, appropriate measures should be taken to ensure the children concerned participate regularly in school sport activities, while taking their individual and current fitness into account.

1.5.4 Rehabilitation

Outpatient or inpatient pneumological rehabilitation is a process, whereby patients suffering from bronchial asthma are given support by a multi-disciplinary team, enabling them to achieve and maintain their best possible level of physical and psychical health, 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 bronchial asthma 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 bronchial asthma 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 Psychological, psychosomatic and psychosocial care

On account of the complex interaction between somatic, psychological and social factors affecting patients with bronchial asthma, 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.

1.5.6 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.

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.

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

1.5.6.1 Regular therapy

The following substances or substance groups should be used primarily for regular therapy purposes:

– inhaled glucocorticosteroids \(^{10}\), \(^{11}\), \(^{12}\), \(^{13}\), \(^{14}\), \(^{15}\), \(^{16}\) (beclomethasone, budesonide, fluticasone) (basic therapy),

the following can be considered as options for supplementing the basic therapy:
- inhaled long-acting beta-2 sympathomimetics \(^{17},^{18},^{19},^{20},^{21},^{22}\), (formoterol, salmeterol),

in justified cases:
- systemic glucocorticosteroids,
- leukotriene antagonists \(^{23},^{24},^{25}\) (montelukast), theophylline (in a delayed-release form).

Following initial instruction in inhalation techniques, these should be monitored at least once in every documentation period.
Should it prove impossible to execute a therapy using inhaled glucocorticosteroids as basic medication (e.g. due to rejection or intolerance on the part of the given patient), a discussion should be held with the patient to clarify the risks involved in prescribing an inferior alternative, anti-inflammatory medication.

1.5.6.2 As-needed therapy

The following groups of substances should be used primarily for as-needed therapy purposes:

– short-acting beta-2 sympathomimetics\(^{26}\), (fenoterol, salbutamol, terbutalin) (preferably by way of inhalation),
in justified cases:
– short-acting anticholinergics\(^{1}\),\(^{27}\),\(^{28}\) (ipratropiumbromide),
– theophylline (in a quick-release form),
– systemic glucocorticosteroids (for a maximum of 1 to 2 weeks).

1.5.6.3 Specific immunotherapy / hyposensitisation

If the symptoms of allergic bronchial asthma cannot be eliminated or reduced to a sufficient extent by avoiding allergens and using pharmacotherapy, the doctor should check whether a specific immunotherapy/hyposensitisation is indicated.

1.5.6.4 Immunisations

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

1.6 Cooperation of the various care provision sectors

The treatment of patients with chronic bronchial asthma 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 bronchial asthma 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 an appropriately qualified specialist 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,
– termination of a regular anti-inflammatory therapy,
– associated disorders (e.g. COPD, chronic sinusitis, recurrent pseudocroup),
– suspected allergic origin of bronchial asthma,
– suspected occupational bronchial asthma,
– aggravation of bronchial asthma during pregnancy.

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 (both adults and children/juveniles) to immediately undergo inpatient treatment include above all the following:

– suspected life-threatening attack,
– serious, persistent attack despite initial treatment.

Moreover, inpatient treatment should be given particular consideration in the following cases:

– suspected serious pulmonary infections,
– in adults: decrease in peak flow to below approx. 30% of the personal best level or to below 100 l/min \(^{29}\), respiratory rate greater than approx. 25 breaths per minute, dyspnoea while speaking and/or significantly diminished breath sounds,
– in children and juveniles: decrease in peak flow to below approx. 50% of the personal best level, lack of response to short-acting beta-2 sympathomimetics, significant drop of oxygen saturation, dyspnoea while speaking, use of auxiliary respiratory muscles, significant increase of heart and respiratory rates and/or significantly diminished breath sounds,
– in pregnant asthmatics with suspected endangerment of the unborn child.

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 bronchial asthma 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 \(^{30}\), \(^{31}\), \(^{32}\), \(^{33}\), \(^{34}\), \(^{35}\).

As far as children and juveniles are concerned, rehabilitation services should also be given due consideration in the event that the disease threatens to disturb the performance and development of the child/juvenile concerned.

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 bronchial asthma would benefit from enrolment in respect of the therapy objectives

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32) Grootendorst DC et al.: Benefits of high altitude allergen avoidance in atopic adolescents with moderate to severe asthma, over and above treatment with high dose inhaled steroids. Clin Exp Allergy 2001; 31: 400-408.
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 with the further requirement that the declaration of participation for insured persons up to and including 15 years of age should be submitted by their legal representatives.

3.2 Special participation requirements

As far as a diagnosis in respect of enrolment is concerned, the existence of a current asthma-typical case history or one dating back no longer than twelve months in accordance with Item 1.2.1 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.

In the case of adult patients, compliance with at least one of the following criteria is required:

– evidence of obstruction with FEV₁/VC < 70% and evidence of (partial) reversibility through an increase of FEV₁ by at least 15% and at least 200 ml after inhalation of a short-acting beta-2 sympathomimetic,
– increase of FEV₁ by at least 15% and at least 200 ml after administration of systemic glucocorticosteroids for up to 14 days or administration of inhaled glucocorticosteroids for up to 28 days 4),
– circadian PEF variability > 20% for 3 to 14 days,
– evidence of bronchial hyperreactivity via a non-specific, standardised, multi-stage inhalational provocation test.

For patients aged between 5 and 17, compliance with at least one of the following criteria is required:

– evidence of obstruction with FEV₁/VC < 75% and evidence of (partial) reversibility through an increase of FEV₁ by at least 15% after inhalation of a short-acting beta-2 sympathomimetic,
– increase of FEV₁ by at least 15% after administration of systemic glucocorticosteroids for up to 14 days or administration of inhaled glucocorticosteroids for up to 28 days 4),
– circadian PEF variability > 20% for 3 to 14 days,
– evidence of bronchial hyperreactivity via a non-specific, standardised, non-inhalational or via a non-specific, standardised, multi-stage inhalational provocation test.

A patient with bronchial asthma subject to standard medication at the time concerned may be enrolled providing the diagnosis was made prior to commencement of the therapy in accordance with Item 1.2.2 and an asthma-typical case history dating from within the last twelve months prior to enrolment is available. Simultaneous enrolment in Part I (bronchial asthma) and Part II (COPD) of the Disease Management Programme is not possible. After a twelve-month period free from symptoms and without asthma-specific therapy, the doctor should check whether the patient concerned continues to benefit from enrolment in the programme and is still able to actively support its realisation in respect of the therapy objectives mentioned under Item 1.3.

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 bronchial asthma 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. Training programmes for children should and training programmes for juveniles may provide for the option of also
training those persons who look after the children or juveniles on a continuous basis. 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.