



# **National Programme for Disease Management Guidelines**

**Responsible institutions:**

**German Medical Association**

**National Association of Statutory Health Insurance Physicians**

**Association of Scientific Medical Societies**

**National Disease Management Guideline**

## **Low back pain**

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## VALIDITY AND FURTHER DEVELOPMENT

This guideline was approved by the Extended Planning Group of the AQuMed (Managing Committee of the National Programme for Disease Management Guidelines) on 4 October 2010 and will remain valid until the next revision or 5 October 2015. The Executive Board of the German Medical Association adopted this guideline on 22 October 2010 as the guideline for the German Medical Association.

The Agency for Quality in Medicine (AQuMed) and the Guideline Committee of the Association of Scientific Medical Societies (AWMF) share responsibility for continuously developing and revising the guideline and communicating changes.

Some topics could not be treated in this guideline due to time constraints, but are nonetheless considered to be essential for the guideline's further development:

- 'gender aspects'
- 'low back pain during pregnancy'

The treatment of these topics is expected to begin during the revision process – preferably before the validity period expires.

### Previous updates of the short version of the National Disease Management Guideline 'Low back pain', 1st edition:

- **Version 4, August 2013:** Amendment due to the ruling of suspension for medicinal products containing tetrazepam, extension of the validity period from four to five years for all NDMG in principle, new version numbering, addition of the DOI, editorial changes
- **Version 1.2, August 2011:** On p. 96 of the Long Version, Chapter H 6.1.4 'Other Analgesics', the frequency of the daily flupirtin intake in the cited study was added in the paragraph concerning flupirtin.
- **Version 1.1, June 2011:** Symbol change for negative recommendations; editorial changes

## VERSIONS OF THE GUIDELINE

The published National Disease Management Guideline (NDMG) 'Low back pain' includes the following components:

- NDMG Short Version including key points on disease management and graduated recommendations
- NDMG Long Version including evidence grades and links to references in addition to Short Version content
- NDMG Guidelines Report
- NDMG Patient Guideline
- NDMG Practice Aids, e.g. summarised information for medical staff/pocket versions for physicians

All versions are available via the home page of the NDMG Programme at <http://www.versorgungsleitlinien.de>.

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**Special note:**

As medical sciences are subject to constant change, any information, especially on diagnostic and therapeutic procedures, can only reflect the state of knowledge at the time of the NDMG's publication. The recommendations given on therapy and drug choice and dosing were drafted with the greatest possible care. Users of this guideline are nevertheless encouraged to refer to the package leaflet and specialized information as a reference and to consult a specialist when in doubt. In the general interest, the NDMG Editorial Office should be informed about potential discrepancies.

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## Table of Contents

<b>I.</b>	<b>Objectives, target groups and scope .....</b>	<b>8</b>
	Rationale .....	8
	Aims and objectives .....	8
	Scope .....	10
<b>II.</b>	<b>List of abbreviations.....</b>	<b>11</b>
<b>1.</b>	<b>Definition, epidemiology and socioeconomic impact .....</b>	<b>12</b>
	Definition .....	12
	Epidemiology and socioeconomic impact.....	12
<b>2.</b>	<b>Management of low back pain .....</b>	<b>13</b>
	Management of acute and subacute nonspecific low back pain .....	13
	Management of chronic nonspecific low back pain .....	13
<b>3.</b>	<b>Diagnostics of low back pain.....</b>	<b>14</b>
	Diagnostic goals.....	14
	Evaluation of medical history .....	15
	Physical examination in low back pain .....	17
	Further investigations.....	19
	Extended examination in chronic low back pain .....	20
	Disease monitoring and long-term care for low back pain patients .....	20
<b>4.</b>	<b>Key points for the therapy of nonspecific low back pain.....</b>	<b>21</b>
<b>5.</b>	<b>Nondrug therapy of nonspecific low back pain .....</b>	<b>22</b>
	Acupuncture .....	22
	Bed rest.....	22
	Physical activity and movement therapy.....	23
	Electrotherapy .....	23
	Relaxation techniques (progressive muscle relaxation) .....	24
	Occupational therapy .....	25
	Short-wave diathermy .....	25
	Laser therapy .....	25
	Magnetic field therapy.....	26
	Manipulation/mobilisation .....	26
	Massage .....	26
	Orthesis.....	26
	Patient education (see also NDMG Patient Guideline).....	27
	Back school.....	27
	Thermo therapy (heat therapy/ cold therapy) .....	28
	Instrumental traction .....	29
	Ultrasound therapy.....	29
	Behavioural therapy .....	29
<b>6.</b>	<b>Drug therapy of nonspecific low back pain.....</b>	<b>30</b>
	Analgesics (nonopioids).....	30
	Opioid analgesics.....	33
	Muscle relaxants .....	33

Antidepressants and other psychopharmaceuticals .....	34
Antiepileptic medications .....	34
Phytotherapeutics .....	34
Percutaneously administered drugs .....	35
Other intravenously administered drugs .....	35
<b>7. Invasive therapy.....</b>	<b>36</b>
<b>8. Prevention of low back pain .....</b>	<b>37</b>
Physical activity.....	37
Education (information/training) .....	37
Ergonomics .....	37
<b>9. Multimodal, multi- and interdisciplinary treatment/rehabilitation .....</b>	<b>39</b>
Definition .....	39
Aims .....	39
Scope.....	40
Indications.....	40
Access .....	41
Post-rehabilitation support .....	41
Re-integration into employment for nonspecific low back pain .....	42
<b>10. Care coordination .....</b>	<b>44</b>
Care coordination for acute low back pain.....	44
<b>11. Quality requirements, quality management and implementation of the guideline .....</b>	<b>53</b>
<b>Appendix 1: Selection of sources and derivation of recommendations.....</b>	<b>56</b>
<b>Appendix 2: Experts responsible for the guideline .....</b>	<b>59</b>
<b>Literature .....</b>	<b>61</b>

## I. Objectives, target groups and scope

National Disease Management Guidelines are evidence-based, clinical decision-making aids for providing structured medical care in the German health care system.

### Rationale

Low back pain is a frequent cause for individuals to seek medical care in Germany. It accounts for high direct costs associated with clinical diagnostics and therapy as well as high indirect costs due to the inability to work and early retirement. The high rate of occurrence of low back pain has led to many different therapies being offered, some of which have been thoroughly studied in recent years. Despite the numerous randomized controlled trials, systemic reviews and national and international guidelines, health care nevertheless needs to be optimized on all levels for patients with nonspecific low back pain. In particular, further action should be taken in the integration of primary and secondary health care levels for enabling inter- or multidisciplinary assessments of the treatment situation with regard to 'yellow' or 'red flags' (see Chapter H3 'Diagnostics of low back pain'). Institutions on the tertiary health care level or in the rehabilitation sector also participate in the care of patients with low back pain. This guideline brings together key recommendations of different national/international guideline editors and evidence-based treatment recommendations on certain prioritised problems in care management. In order to take adequate account of the specific characteristics of all levels of care in the German health care system and to increase user acceptance, all care providers were actively involved in the development of this guideline.

### Aims and objectives

The NDMG 'Low back pain' aims to provide guidance in the care of patients with nonspecific low back pain. In keeping with the criteria of evidence-based medicine, the guideline is up to date both scientifically (best currently available evidence) and with regard to practice. It is directed at physicians and nonmedical health care professionals in all sectors.

Affected individuals and their families are also addressed by means of a specially developed Patient Guideline.

Each chapter of the NDMG 'Low back pain' was written with health care requirements and currently available treatments in mind. This NDMG also provides guidance in the integrated care of low back pain patients across all sectors by giving recommendations on how to improve coordination between each area of care.

This guideline has the following disease-specific goals:

### Structural quality

1. Recommendations on how to document and describe interfaces in the treatment of patients with nonspecific low back pain are given in order to improve cooperation among outpatient, inpatient and rehabilitation sectors, between general practitioners and specialists and among all professional care providers.

### Procedural quality

2. To ensure early detection, the NDMG labels serious underlying aetiologies with 'red flags' that should be taken note of in all patients. They are intended to warn the physician of the presence of a potentially serious disease and lead to further diagnostic evaluation and therapy.
3. To demonstrate effective ways of preventing nonspecific low back pain.
4. To advise care providers on how to identify risk factors for pain persistence and chronification in the initial phase of the disease. At this stage, greater attention should already be paid to psychosocial management.
5. To provide relevant information that will permit all care providers and patients to have a biopsychosocial understanding of nonspecific low back pain.
6. To provide recommendations and advice on the use of learning and training material that reinforces the necessary degree of awareness for improving the understanding of the disease and, accordingly, adherence to therapy and the patient's acceptance of responsibility.
7. To provide recommendations and information about evidence-based diagnostic tests on nonspecific low back pain in order to reduce the use of ineffective diagnostic methods.
8. To provide therapeutic recommendations aimed at supporting complaint-oriented and individualized therapies for low back pain. These are oriented toward pain control and the urgent restoration of function.
9. To provide information on therapies without proven effect in order to prevent the administration of unnecessary and obsolete methods.
10. To provide recommendations and information on the benefits of physical training in the prevention and treatment of nonspecific low back pain in order to improve, both quantitatively and qualitatively, the affected individuals' acceptance of opportunities for physical exercise.
11. To provide recommendations on appropriate multimodal, multi- and interdisciplinary treatment methods aimed at improving self-management and participation in social and working life.

### Quality of results

12. To provide recommendations and information on evidence-based therapies for nonspecific low back pain in order to improve the quality of life in affected individuals.
13. To provide recommendations and information on evidence-based therapies for nonspecific low back pain in order to reduce the proportion of disability and lower earning capacity caused by low back pain.
14. To provide recommendations and information on the diagnostics and treatment of nonspecific low back pain in order to reduce the proportion of low back pain chronification.
15. To streamline and improve treatment workflows in order to establish the basis for a long-term reduction of health care costs linked to low back pain.

## Scope

### The recommendations of the guideline are intended for:

- all medical professions involved in the detection, diagnosis and treatment of patients with low back pain:
  - primary care (areas: internal medicine and general medicine or internal medicine without subspecialisation, physicians without field designation)
  - specialities (areas: orthopaedics and trauma surgery or physical and rehabilitative medicine)
  - complimentary specialities (areas: gynaecology, internal medicine and haematology and oncology, internal medicine and rheumatology, neurosurgery, neurology, orthopaedics and trauma surgery, radiology with or without specialist competency in neuroradiology, advanced training in pain therapy)
- treatment-support specialists (e.g. areas: occupational therapy, physiotherapy, psychological psychotherapy, social work/social pedagogy/sociotherapy)
- specialty hospitals and departments (e.g. spine surgical outpatient service, pain-therapeutic centres), acute and rehabilitative hospitals for psychosomatic medicine as well as other rehabilitative centres
- adults affected by low back pain and their relatives
- decision-makers in the health care system
- members of the general public seeking information on good diagnostic/therapeutic strategies

### The guideline is also intended for:

- parties contractually responsible for 'disease management programmes' and 'integrated health care contracts'
- medical scientific societies and other editors whose own guidelines form the basis for NDMG

## II. List of abbreviations

AQuMed	Agency for Quality in Medicine
AWMF	Association of the Scientific Medical Societies in Germany
COX-2	Cyclooxygenase-2
NDMG	National Disease Management Guideline
NRS	Numeric Rating Scale
PENS	Percutaneous Electrical Nerve Stimulation
PMR	Progressive Muscle Relaxation
TENS	Transcutaneous Electrical Nerve Stimulation
tNSAR	Traditional nonsteroidal antirheumatics/antiphlogistics
VAS	Visual Analogue Scale

## 1. Definition, epidemiology and socioeconomic impact

In general, back pain is pain of varying intensity felt in the human back, which can have many different causes.

### Definition

The scope of this guideline is the care of patients with nonspecific low back pain. Nonspecific low back pain may be classified by cause, duration, intensity and chronification stage and is characterized by:

- pain in the back between costal arch and gluteal fold, with or without spreading pain
- missing evidence of specific causes
- acute low back pain (less than 6 weeks duration)
- subacute pain episodes (more than 6 weeks duration)
- chronic or chronic recurrent low back pain (more than 12 weeks duration)
- possible varying pain intensity
- possible other related complaints

The Numerical Rating Scale (NRS) or the Visual Analogous Scale (VAS) are recommended for the measurement of severity in the acute stage. The severity of chronic low back pain is graded according to Korff et al. [1].

### Epidemiology and socioeconomic impact

Low back pain is one of the most frequent types of pain. Typically, affected individuals report prolonged sickness, often in the form of multiple, recurrent episodes. A maximum of one fourth of the total prevalence is related to continual chronic low back pain. Women are affected more frequently than men. Several German studies show a decrease in morbidity rates between the sixth and seventh decade of life [2].

Low back pain causes direct costs of 8.4 billion euros each year. Productivity losses owing to the inability to work and the incapacity to earn an income are estimated to account for 85% of the total costs, and approximately 15% of the total costs is spent on medical treatment. Low back pain is the number one reason for an inability to work and medical rehabilitation [3].

## 2. Management of low back pain

In the management of low back pain, a distinction must be made between acute and chronic disease.

### Management of acute and subacute nonspecific low back pain

The disease management objectives include:

- detecting warning signs of preventable serious illness ('red flags') as soon as possible in order to investigate the aetiology in more detail where applicable and to refer to targeted treatment (see Chapter H 3 'Diagnostics of low back pain')
- adequate symptom control, e.g. relief of pain, so that patients may resume their daily activities as quickly as possible
- actively detecting warning signs of existing psychosocial risk factors ('yellow flags')
- preventing chronification (for 'yellow flags': to promote adequate [biopsychosocial] understanding of the disease)
- avoiding ineffective diagnostics procedures
- avoiding the risk of iatrogenic fixation

### Management of chronic nonspecific low back pain

The disease management objectives include:

- detecting warning signs of preventable serious illness ('red flags') or any specifically treatable diseases
- maintaining an adequate (biopsychosocial) understanding of the disease
- sharing the same model of the disease and encouraging active patient participation
- preventing harmful patient behaviour
- promptly initiating a somatic therapeutic strategy and comprehensive education by the treating physicians, using psychotherapeutic intervention if necessary
- maintaining or restoring the ability to work and earn an income
- advising on the sociomedical effects of the disease in view of the work situation
- avoiding or minimizing disability or the need for nursing care


### 3. Diagnostics of low back pain

This NDMG is restricted to the diagnostics and therapy of nonspecific low back pain. The diagnostics and therapy of specific low back pain are not within the scope of this NDMG. They are included only to point out preventable serious illness and specifically manageable aetiologies.

#### Diagnostic goals

The diagnostics of low back pain serves various goals:

- to reveal the causes of low back pain, in particular if they require specific or even urgent treatment (see Table 1)
- to objectify the complaints and any resulting functional disorders as a basis for disease monitoring; for this purpose standardised questionnaires and/or documentation forms may be useful
- to reveal factors bearing a risk for developing chronic pain ('yellow flags')

Recommendation/statement	Grade of recommendation
<b>3-1</b> If medical history and clinical assessment do not reveal any signs of serious illness and other serious pathologies, do not carry out further diagnostic investigations for the time being. Classify the complaints as nonspecific low back pain for the time being.	

## Evaluation of medical history

The medical history is to be evaluated in detail at the beginning of the diagnostic process. This should include information on **pain characteristics**. To identify preventable serious diseases, patients should always be queried about **concomitant symptoms and previous diseases** that may warn the physician of specific aetiologies in urgent need of treatment (**'red flags'**).

**Table 1: Warning signs of specific aetiologies originating in the spine that are frequently in urgent need of treatment ('red flags'), modified according to the recommendations for the therapy of low back pain – AkdÄ [4]**

Fracture	Tumour	Infection	Radiculopathies/ neuropathies
<ul style="list-style-type: none"> <li>serious trauma, e.g. through a car accident, fall from a great height, sports accident</li> <li>minor trauma (e.g. coughing, sneezing, heavy lifting in elderly, potential osteoporosis patients)</li> <li>systemic steroid therapy</li> </ul>	<ul style="list-style-type: none"> <li>old age</li> <li>history of malignancies</li> <li>general symptoms: loss of weight, reduced appetite, rapid fatigue</li> <li>pain, increasing in supine position</li> <li>intense nocturnal pain</li> </ul>	<ul style="list-style-type: none"> <li>general symptoms such as recent fever, chills, reduced appetite, rapid fatigue</li> <li>previous bacterial infections</li> <li>IV drug abuse</li> <li>immunosuppression</li> <li>consuming underlying diseases</li> <li>very recent spinal infiltration treatment</li> <li>intense nocturnal pain</li> </ul>	<ul style="list-style-type: none"> <li>pain travelling in one or both legs, may be associated with paraesthesia (e.g. sensation of numbness or tingling in secondary areas of pain or feeling of weakness)</li> <li>cauda equina syndrome: <ul style="list-style-type: none"> <li>sudden bladder-/rectal disorder, e.g. urinary retention, frequent urination, incontinence</li> <li>paraesthesia perianal/perineal</li> </ul> </li> <li>pronounced or increasing neurological deficiency (paralysis, sensory disorder) of the lower extremities (see Table 4)</li> <li>decreasing pain and increasing paralysis, ultimately complete functional loss of the identification muscle (nerve root death)</li> </ul>

## Risk factors for developing chronic pain in acute low back pain ('yellow flags')

Psychosocial and somatic risk factors for pain chronification ('yellow flags') are assessed during the care process. Indicators that are primarily independent of pain (depressiveness, workplace satisfaction) may be evaluated on the first day individuals seek medical attention for acute low back pain. Pain-related indicators such as pain-related cognition or specific pain behaviour assume that a patient's pain experience has lasted for some time.

**Table 2: Psychosocial risk factors for developing chronic nonspecific low back pain**

<b>Strong evidence<sup>1</sup></b>	<ul style="list-style-type: none"> <li>• depressiveness, distress (negative stress, mainly job and work related)</li> <li>• pain-related cognition (e.g. catastrophizing,<sup>2</sup> help- or hopelessness, fear-avoidance beliefs<sup>2</sup>)</li> <li>• passive pain behaviour (e.g. strong tendency to spare oneself and avoidance behaviour)</li> </ul>
<b>Moderate evidence</b>	<ul style="list-style-type: none"> <li>• pain-related cognition: thought suppression<sup>2</sup></li> <li>• overactive pain behaviour: task persistence,<sup>2</sup> suppressive pain behaviour</li> <li>• tendency toward somatisation</li> </ul>
<b>Limited evidence</b>	<ul style="list-style-type: none"> <li>• personality traits</li> </ul>
<b>No evidence</b>	<ul style="list-style-type: none"> <li>• psychopathological disorders</li> </ul>

Besides psychosocial risk factors, other factors contribute to the development of chronic low back pain.

**Table 3: Other risk factors for the chronification of low back pain**

### Workplace-related factors

- predominantly heavy physical labour (carrying, lifting of heavy loads) [7]
- predominantly monotonous body posture [7]
- predominant exposure to vibration [7]
- unskilled work
- work dissatisfaction
- loss of employment
- offensive work relationships, harassment

### Iatrogenic factors

- insufficient respect for a multifactorial causality
- overestimating somatic/radiologic findings in the case of nonspecific pain
- prolonged sick leave that is hard to justify
- promoting passive therapy concepts
- excessive use of diagnostic procedures

<sup>1</sup> according to van Tulder et al., 1997 [5; 6]

<sup>2</sup> see glossary

Various risk-screening instruments have been developed (Musculoskeletal Pain Screening Questionnaire [MPSQ], Heidelberg Short Questionnaire Back Pain [HKF-R 10] and Risk Analysis of Pain Chronification – Back [RISC-R]). They are available at <http://www.versorgungsleitlinien.de>.

Recommendation/statement	Grade of recommendation
<b>3-2</b> If pain persists for more than 4 weeks <sup>3</sup> despite guideline-compliant measures, assess psychosocial risk factors already during primary care.	↑↑
<b>3-3</b> In the event of sustained pain (>12 weeks), continue with somatic diagnostics and assess psychosocial influencing factors (optimally on the basis of inter-/multidisciplinary assessments).	↑↑
















## Physical examination in low back pain

Physical examination in the case of low back pain serves to help identify specific aetiologies and exclude the presence of preventable serious illness (see Table 1). The extent of the physical examination depends on the results of the medical history:

- If aetiologies not originating in the spine are likely to cause the pain, the respective organ systems should be examined.
- If the medical history is suggestive of trauma, malignancy, infection, concomitant radicular compression or cauda equina syndrome, these are to be investigated.
- If the medical history is inconspicuous (no 'red flags') and the patient reports complaints in the back without current or previous indications of nerve compression (with associated signs and symptoms such as pain spreading in the leg), basis diagnostics is sufficient.

<sup>3</sup> Inability to work may be investigated earlier

Table 4: Characteristics of the most frequent lumbosacral compression syndromes

Pain paraesthesias	Sensory disorders	Paresis	Muscle idioreflexes	
			PSR ↓ 	<b>L4 Syndrome</b>
		Heel position ↓ 	Tibialis post- Reflex ↓ 	<b>L5 Syndrome</b>
		Tip-toe position ↓ 	ASR ↓ 	<b>S1 Syndrome</b>
		Paralysis of the bladder, rectum  Saddle block anaesthesia  Bilateral leg paresis	ASR ↓ 	<b>Cauda equina syndrome</b>

Illustrations adapted. Source: Mumenthaler, M., Schliack, T., Stöhr, M.: Läsionen peripherer Nerven und radikuläre Syndrome, 1998, Thieme Verlag, 7th ed.

## Further investigations

Recommendation/statement	Grade of recommendation
<b>3-4</b> If warning signs exist, initiate further laboratory investigations or imaging tests and/or refer to a specialist, depending on the suspected diagnosis and medical urgency.	↑↑↑

## Imaging techniques

The uncritical application of imaging techniques is associated with high direct and indirect costs [8]: these involve primary costs based on the examination, but above all subsequent costs attributed to chronification or procedures that are not indicated.

The guidelines used as a source for this NDMG [4; 9; 10] consistently disapprove of the routine use of imaging methods.

### Acute low back pain

Recommendation/statement	Grade of recommendation
<b>3-5</b> Do not perform imaging techniques in acute low back pain if there is no indication of serious illness based on medical history and physical examination.	↑↑↑
<b>3-6</b> If warning signs are present ('red flags'), perform an appropriate imaging procedure.	↑↑↑

### Subacute low back pain

Recommendation/statement	Grade of recommendation
<b>3-7</b> If severe and disabling low back pain does not improve after 6 weeks of guideline-compliant therapy, conduct a one-time diagnostic imaging.	↑↑↑

### Chronic low back pain

Recommendation/statement	Grade of recommendation
<b>3-8</b> In instances of chronic low back pain (>12 weeks) despite guideline-compliant therapy, apply diagnostic imaging once (if not done already) after exclusion of psychosocial chronification factors.	↑↑↑
<b>3-9</b> If psychological chronification factors exist in low back pain persisting more than 12 weeks, diagnostic imaging is only indicated for patients showing clinical signs of organ pathologies.	↑↑↑

## Laboratory investigations

Laboratory investigations to exclude inflammatory or neoplastic aetiologies are not recommended on a routine basis [11].

In chronic low back pain of unclear aetiology with onset before the age of 45, the determination of HLA-B27 is diagnostically useful (positive predictive value is higher if patient is asked about signs of inflammatory low back pain before).

## Extended examination in chronic low back pain

The following methods are reasonable additional assessments for disease monitoring in speciality care:

- measurement of functional ability (Functional Ability Questionnaire Hannover–Back [FFbH-R]) [12]
- measurement of pain severity (grading the severity of chronic pain according to Korff et al.) [1]
- measurement of the chronification stage (Mainz Pain Staging System [MPSS]) [13]
- German Pain Questionnaire [14]

The instruments that are public domain are available at <http://www.versorgungsleitlinien.de>.

## Disease monitoring and long-term care for low back pain patients

The long-term care of patients with low back pain should be provided by inter-/multidisciplinary teams. These treatment teams continually carry out the following tasks:

- education and information about health-promoting habits including regular physical activity
- prevention of medical procedures provoking chronification

A particularly long-term need for care develops in the following situations:

- administration of drugs for prolonged time to treat low back pain (>4 weeks)
- discharge from an outpatient or inpatient pain-therapeutic intervention centre or a rehabilitation facility (generally with recommendations for further treatment)
- remaining chronification factors and/or psychosocial side effects attributable to the pain
- the presence of comorbidities maintaining or reinforcing symptoms

## 4. Key points for the therapy of nonspecific low back pain

As there are by definition no signs of specific causes in nonspecific low back pain, the therapy is focused on signs and symptoms. There are **nondrug** and **drug** interventions in this therapy.

The basic principles are:

- The therapy of nonspecific low back pain focuses on the activation of the patient. It is particularly important to screen for risk factors of chronification in acute low back pain ('yellow flags').
- As monomodal treatment approaches precede the patient's exclusively somatic attribution of low back pain, multi- and interdisciplinary treatment plans are developed and implemented as soon as possible.
- The therapy is adapted to the pain and present functional status. A treatment plan must be coordinated between the involved physicians and the patient and requires the patient's understanding and active cooperation. When planning the therapy, patient preferences may therefore be considered by the treating team.
- Drug therapy should support nondrug therapy in the acute stage in order to enable the patient to resume his/her usual activities. Drug therapy in chronic low back pain is indicated if pain therapy is necessary for the successful activation of the patient (see Chapter H 5 'Nondrug therapy of nonspecific low back pain' and Chapter H 9 'Multimodal, multi- and interdisciplinary therapy/rehabilitation').
- Optional treatment recommendations (terminology: 'may') are considered only after all therapeutic methods with a higher recommendation grade have been exhausted.

## 5. Nondrug therapy of nonspecific low back pain

Besides physical activity, consultation and drug therapy, there are numerous nondrug therapies that may support the treatment of acute, subacute and chronic nonspecific low back pain.

During the consensus process, recommendation grades may be justifiably raised or lowered in relation to the evidence class. As scientific evidence was frequently insufficient and/or contradictory, recommendation grades were determined by weighing risks and benefits. Individual explanations are given as comments below the respective recommendations (see also Appendix 1).

### Acupuncture

Recommendation/statement	Grade of recommendation
<b>5-1</b> Do not use acupuncture in the treatment of acute nonspecific low back pain.	↓↓↓

*Comment:* The aim of the management of acute nonspecific low back pain is to prevent medicalisation and to focus on the key recommendations (consultation, drugs against pain, physical activity). Acupuncture is not an activating method. Standard acupuncture therapy involves several sessions (usually 6-10). In the instance of acute disease where there may be quick improvement, this is counterproductive or often not feasible. As acute nonspecific low back pain symptoms are mostly self-limiting, treatment with acupuncture is not compatible with an economical expenditure of scarce resources. The resources are better spent on patients with chronic pain.

Recommendation/statement	Grade of recommendation
<b>5-2</b> Acupuncture has only very limited application in chronic nonspecific low back pain.	↔

*Comment:* This type of therapy is time consuming for the patient and it is not possible to transition to autonomous activities. Patients depend on therapists, and there are not only different schools of acupuncture, but also a wide range of qualitative standards in the exercise of this technique. Furthermore, the effective mechanisms of acupuncture that produce a therapeutic effect – such as needle placement or other factors such as the stimulus parameters of the needling or physician-patient interactions – are presently unclear.

### Bed rest

Recommendation/statement	Grade of recommendation
<b>5-3</b> Do not use bed rest for treating acute nonspecific low back pain. Advise patients with acute nonspecific low back pain against bed rest.	↓↓↓

*Comment:* In the instance of nonspecific low back pain, the continuation or resumption of daily physical activities is encouraged because physical activity improves symptoms and helps prevent the chronification of pain. Bed rest is to be avoided [5; 9; 10; 15]. In some cases, bed rest may be necessary for a few hours or days depending on the severity of the complaints. Physicians are charged with helping the patient to stand up and slowly regain physical activity through rigorous pain therapy [9].

Recommendation/statement	Grade of recommendation
<b>5-4</b> Do not use bed rest in the treatment of chronic nonspecific low back pain. Patients with chronic nonspecific low back pain are to be advised against bed rest.	↓↓↓

*Comment:* Bed rest aggravates passive disease behaviour (see Glossary). The likelihood that frequent bed rest will adversely affect the course of chronic nonspecific low back pain and have other additional side effects (e.g. muscle wasting, thromboembolisms) is therefore high. Bed rest may lead to chronic impairment and prevent rehabilitation. It is strongly recommended that patients maintain their usual level of physical activity or gradually resume physical activity as soon as possible.

## Physical activity and movement therapy

Recommendation/statement	Grade of recommendation
<b>5-5</b> Encourage patients to stay as physically active as possible.	↑↑↑
<b>5-6</b> Do not prescribe movement therapy (including physiotherapy) in the treatment of acute nonspecific low back pain.	↓↓↓
<b>5-7</b> Movement therapy is to be used in the primary treatment of subacute/chronic nonspecific low back pain.	↑↑↑

*Comment:* Controlled movement therapy is used in the treatment of functional disorders relating to posture and motor organs. Mobilising and stabilising techniques are performed to improve mobility, coordination, muscle power, fitness and rapid muscle strength. Controlled movement therapy is also used to eliminate or minimize skills deficits by developing and mastering the most efficient movement sequences. Controlled movement therapy is a dynamic process aimed at continuously building up physical capacity and restoring normal body function through a systematic and step-wise manner of treatment.

## Electrotherapy

The term electrotherapy applies to interference therapy, transcutaneous electrical nerve stimulation (TENS) and percutaneous electrical nerve stimulation (PENS).

### Interference therapy

Recommendation/statement	Grade of recommendation
<b>5-8</b> Do not use interference therapy in the treatment of acute/subacute nonspecific low back pain.	↓↓↓
<b>5-9</b> Do not use interference therapy in the treatment of chronic nonspecific low back pain.	↓↓↓

### Percutaneous electrical nerve stimulation (PENS)

Recommendation/statement	Grade of recommendation
<b>5-10</b> Do not use PENS in the treatment of acute nonspecific low back pain.	↓↓↓

*Comment:* There is no published evidence on the benefits of PENS in the treatment of acute nonspecific low back pain. Furthermore, this type of therapy fosters passive patient behaviour and thus contradicts the primary treatment goal of patient activation.

Recommendation/statement	Grade of recommendation
<b>5-11</b> Do not use PENS in the treatment of chronic nonspecific low back pain.	↓↓↓

*Comment:* One study seems to support the efficacy of PENS, but the evidence is considered insufficient given that the population sample (n=34, ≥65 years old) does not represent the entire target group of patients with nonspecific low back pain. Even the larger sample in the end only compares 4 groups with only 50 persons each. The study's design is questionable with regard to blinding and control intervention. It is not clear which effects cause the measured improvements in the studied population. Furthermore, the use of PENS fosters passivity and thus contradicts the primary treatment goal of patient activation.

## Transcutaneous electrical nerve stimulation (TENS)

Recommendation/statement	Grade of recommendation
<b>5-12</b> Do not use TENS in the treatment of acute nonspecific low back pain.	↓↓↓

*Comment:* There is no published evidence on the benefits of TENS in the treatment of acute nonspecific low back pain. This type of therapy fosters passive patient behaviour and thus contradicts the primary treatment goal of patient activation.

Recommendation/statement	Grade of recommendation
<b>5-13</b> Transcutaneous electrical nerve stimulation should not be used in the treatment of chronic nonspecific low back pain.	↓↓

## Relaxation techniques (progressive muscle relaxation)

Recommendation/statement	Grade of recommendation
<b>5-14</b> In the case of increased risk of chronification, progressive muscle relaxation (PMR) may be offered in the treatment of acute/subacute low back pain.	↔

*Comment:* The use of relaxation techniques for the treatment of acute low back pain is limited as the training of fast and deep relaxation can take several weeks. Patients already showing signs of intense muscle tension, stress and/or vegetative disorders should be offered muscle relaxation at this stage precisely because of the expected duration of the exercise. Chronic pain may be effectively prevented this way or its symptoms alleviated.

Recommendation/statement	Grade of recommendation
<b>5-15</b> The relaxation technique PMR should be used in the treatment of chronic nonspecific low back pain.	↑↑

## Occupational therapy

Recommendation/statement	Grade of recommendation
<b>5-16</b> Do not use occupational therapy in the treatment of acute nonspecific low back pain.	↓↓↓
<b>5-17</b> Occupational therapy should be used in the treatment of chronic nonspecific low back pain as part of a multimodal treatment programme.	↑↑

## Short-wave diathermy

Recommendation/statement	Grade of recommendation
<b>5-18</b> Do not use short-wave diathermy in the treatment of acute nonspecific low back pain.	↓↓↓
<b>5-19</b> Do not use short-wave diathermy in the treatment of chronic nonspecific low back pain.	↓↓↓

*Comment:* There is no published evidence on the benefits of short-wave diathermy in the treatment of chronic nonspecific low back pain. Furthermore, this type of therapy fosters passive patient behaviour and thus contradicts the primary treatment goal of patient activation.

## Laser therapy

Recommendation/statement	Grade of recommendation
<b>5-20</b> Do not use laser therapy in the treatment of acute nonspecific low back pain.	↓↓↓

*Comment:* There is no published evidence for the benefits of laser therapy in the treatment of acute nonspecific low back pain. Furthermore, this type of therapy fosters passive patient behaviour and thus contradicts the primary treatment goal of patient activation.

Recommendation/statement	Grade of recommendation
<b>5-21</b> Do not use laser therapy in the treatment of chronic nonspecific low back pain.	↓↓↓

*Comment:* Studies failed to show that laser therapy produces additive effects beyond the intended effects of movement therapy in the control group. There is no reason for a positive recommendation given that this type of therapy also fosters passive patient behaviour and thus contradicts the primary treatment goal of patient activation.

## Magnetic field therapy

Recommendation/statement	Grade of recommendation
<b>5-22</b> Do not use magnetic field therapy in the treatment of acute nonspecific low back pain.	↓↓↓
<b>5-23</b> Do not use magnetic field therapy in the treatment of chronic nonspecific low back pain.	↓↓↓

## Manipulation/mobilisation

Recommendation/statement	Grade of recommendation
<b>5-24</b> Manipulation/mobilisation may be used in the treatment of acute nonspecific low back pain.	↔
<b>5-25</b> Manipulation/mobilisation may be used in the treatment of chronic nonspecific low back pain in combination with exercise.	↔

## Massage

Recommendation/statement	Grade of recommendation
<b>5-26</b> Do not use massage in the treatment of acute nonspecific low back pain.	↓↓↓

*Comment:* There is no published evidence for the benefits of massage in the treatment of acute nonspecific low back pain. Furthermore, this type of therapy fosters passive patient behaviour and thus undermines the primary treatment goal of patient activation.

Recommendation/statement	Grade of recommendation
<b>5-27</b> Massage may be used in the treatment of subacute/chronic nonspecific low back pain in combination with exercise.	↔

## Orthosis

Recommendation/statement	Grade of recommendation
<b>5-28</b> Do not use orthosis in the treatment of acute nonspecific low back pain.	↓↓↓

*Comment:* There is no published evidence for the benefits of orthosis in the treatment of acute nonspecific low back pain. Furthermore, this type of therapy fosters passive patient behaviour and thus undermines the primary treatment goal of patient activation.

Recommendation/statement	Grade of recommendation
<b>5-29</b> Do not use orthosis in the treatment of chronic nonspecific low back pain.	↓↓↓

## Patient education (see also NDMG Patient Guideline)

Recommendation/statement	Grade of recommendation
<b>5-30</b> Inform and advise patients with acute/subacute nonspecific low back pain adequately and individually.  Adequate consultation covers the following key points: the positive prognosis, the importance of physical activity, the lack of a need for a radiological assessment of the spine, the option of further diagnostic measures in the case of persistence or worsening of complaints.	↑↑

*Comment:* Early appropriate consultation/patient education by the physicians in charge is crucial in the treatment of acute nonspecific low back pain. Most importantly, physicians must explain in a comprehensible way that low back pain is very common, that chances of recovery are generally very good and that pain does not necessarily indicate organ damage [10]. Consultation/education should encourage the patient to continue or resume appropriate physical activity. Although proven benefits are shown in the available studies only in the case of prolonged education (more than 2 hours), consultation performed in the way described above probably presents an important criterion for the prevention of chronification – even if the consultation period is considerably shorter.

Recommendation/statement	Grade of recommendation
<b>5-31</b> In standard care, continue training (consultation/education) patients with chronic nonspecific low back pain (consultation/education). In the training, encourage patients to resume normal physical activities and offer concrete support.	↑↑

*Comment:* Ideally, persons with chronic low back pain are to be treated in multimodal treatment programs. Education/consultation is an essential element of treatment in these programmes. The International Classification of Functioning, Disability and Health [16] succinctly defines the following ‘activities and participation’ categories for the Core Set ‘Low back pain’: maintaining a body position, lifting and carrying objects, changing basic body position, walking, work and employment (other specified and unspecified), doing housework, dressing, handling stress and other psychological demands, acquiring and maintaining family relationships, using the toilet, as well as acquiring, keeping and terminating a job [17]. These activities can be supported in the private practice sector. Giving adequate advice on how to stay physically active, and where required, checking the commitment level of the patient and their ability to cope with obstacles, may contribute to treatment success as means of ongoing support.

## Back school

Attending back schools can only be recommended if they follow the biopsychosocial approach, utilise modern concepts such as fear avoidance and functional restoration and do not work with the classical right-or-wrong dichotomies [18].

As qualified providers run back schools in varying ways with different concepts and points of emphasis, a general statement cannot be made about the quality of back schools. It makes sense for physicians to look into local offerings themselves on an individual basis.

Recommendation/statement	Grade of recommendation
<b>5-32</b> Back school based on a biopsychosocial approach may be recommended in the treatment of sustained nonspecific low back pain (>6 weeks) or recurrent nonspecific low back pain.	↔
<b>5-33</b> Back school based on an exclusively biopsychosocial approach should be offered in the treatment of chronic nonspecific low back pain.	↑

## Thermo therapy (heat therapy/ cold therapy)

Recommendation/statement	Grade of recommendation
<b>5-34</b> Heat therapy may be used in the treatment of acute nonspecific low back pain in combination with activating measures.	↔
<b>5-35</b> Cold therapy should not be used in the treatment of acute nonspecific low back pain.	↓

*Comment:* As other types of locally applied heat (heating pads, heating blankets, heating belts/bandages) have not shown positive effects with regard to pain reduction and functional ability in nonspecific low back pain, the advantage of heat wraps is probably that they do not interfere with normal physical activity. Additional activating measures are therefore required in the use of heat wraps. Heat therapy, however, should only be indicated at the beginning of the disease. Prolonged use increases the risk of 'withdrawal into the disease' (see Glossary: passive disease behaviour).

**Cave!** If heat increases the pain, the diagnosis must be re-evaluated. In the case of tumours and inflammation, pain may become more intense due to hyperaemia [4].

Recommendation/statement	Grade of recommendation
<b>5-36</b> Heat therapy should not be prescribed in the treatment of chronic nonspecific low back pain.	↓
<b>5-37</b> Cold therapy should not be used in the treatment of chronic nonspecific low back pain.	↓

*Comment:* Patients do not need to be discouraged from the self-administration of heat (e.g. through grain pillows, hot water bottles) or cold (e.g. through cool pads). It is likely to contribute to the patient's physical comfort and is not harmful. The prescription of thermo-therapeutic measures is not justified, however, as proof of effectiveness is lacking.

## Instrumental traction

Recommendation/statement	Grade of recommendation
<b>5-38</b> Do not use instrumental traction in acute nonspecific low back pain.	↓↓↓
<b>5-39</b> Do not use instrumental traction in subacute/chronic nonspecific low back pain.	↓↓↓

## Ultrasound therapy

Recommendation/statement	Grade of recommendation
<b>5-40</b> Do not use therapeutic ultrasound in the treatment of acute nonspecific low back pain.	↓↓↓

*Comment:* There is no published evidence for the benefits of therapeutic ultrasound in the treatment of acute nonspecific low back pain. Furthermore, this type of therapy fosters passive patient behaviour and thus undermines the primary treatment goal of patient activation.

Recommendation/statement	Grade of recommendation
<b>5-41</b> Do not use therapeutic ultrasound in the treatment of chronic nonspecific low back pain.	↓↓↓

## Behavioural therapy

Recommendation/statement	Grade of recommendation
<b>5-42</b> If psychosocial risk factors are present in subacute nonspecific low back pain, offer cognitive behavioural therapy based on the individual risk profile.	↑↑↑
<b>5-43</b> Use cognitive behavioural therapy integrated in a multimodal treatment concept in the treatment of patients with chronic nonspecific low back pain.	↑↑↑

## 6. Drug therapy of nonspecific low back pain

Drug therapy in the treatment of nonspecific low back pain is symptomatic. Drugs are intended to support nondrug measures in the acute stage so that patients can quickly resume their usual activities. Drug therapy is indicated for chronic low back pain if pain treatment is necessary for the implementation of activation methods. A medical history of pain characteristics is required for successful pain treatment.

Drug history should be assessed in detail before initiating drug therapy as previous positive experiences and undesired drug effects may influence therapy decisions.

It is important for the therapy that the intake of drugs follows a defined schedule. Drug treatment should be interrupted after a few days to evaluate the need for further therapy.

The VAS or NRS should be used for monitoring pain intensity and therapy evaluation.

Detailed information about undesired side effects, contraindications and interactions between the recommended drugs are summarized in the drug information section of the NDMG Long Version.

### Analgesics (nonopioids)

Depending on the individual diagnostic constellation, paracetamol, different traditional nonsteroidal antirheumatics/antiphlogistics (tNSAR) and COX-2 inhibitors may be used from the group of nonopioid analgesics.

#### Paracetamol

Recommendation/statement	Grade of recommendation
<b>6-1</b> Treatment may be tried with paracetamol, up to a maximum daily dose of 3 g in mild to moderate acute nonspecific low back pain. The outcome of the treatment should be evaluated after a short period.	↔

*Comment:* To avoid the risk of paracetamol intoxication, the recommended maximum dose was reduced to 3 g daily as opposed to the drug prescription information. In the United Kingdom and the USA, paracetamol intoxication has become the most frequent cause of acute liver failure. In the USA, 48% of all cases are attributed to accidental overdosing or the combination with another preparation containing paracetamol. Chronic alcoholism or malnutrition are considered to be supporting factors [4]. Normal therapeutic dosing of paracetamol causes few side effects in comparison to tNSAR. It is therefore particularly important to not exceed the maximum daily dose.

Recommendation/statement	Grade of recommendation
<b>6-2</b> Paracetamol may only be used for subacute and chronic nonspecific low back pain after assessing the drug history and to treat short exacerbations of chronic nonspecific low back pain. It should then only be taken for a short time and at the lowest possible dose.	↔

There are indications that the frequent intake of paracetamol (for more than 21 days per month) increases the risk of elevated blood pressure and cardiac infarction [19]. Combination therapy of tNSAR and paracetamol increases the risk of gastrointestinal ulceration and bleeding [20].

## Traditional nonsteroid antirheumatics/antiphlogistics (tNSAR)

Recommendation/statement	Grade of recommendation
<b>6-3</b> Patients with acute nonspecific low back pain should receive tNSAR for pain relief in a low dose. Effectiveness has been demonstrated for up to 1.2 g ibuprofen, 100 mg diclofenac or 750 mg naproxen daily. In case of an insufficient response, the daily dose may be increased up to 2.4 g ibuprofen, 150 mg diclofenac or 1.25 g naproxen, taking into account potential side effects and undertaking any required prophylactic measures.	↑
<b>6-4</b> If there pharmacotherapy is indicated in chronic nonspecific low back pain, tNSAR should be used in a low dose to relieve pain. Effectiveness has been demonstrated for up to 1.2 g ibuprofen, 100 mg diclofenac or 750 mg naproxen daily. In case of an insufficient response, the daily dose may be increased up to 2.4 g ibuprofen, 150 mg diclofenac or 1.25 g naproxen, taking into account potential side effects and undertaking any required prophylactic measures.	↑
<b>6-5</b> If the treatment with tNSAR coincides with pre-existing gastrointestinal risks, proton pump inhibitors should be administered as a prophylaxis.	↑

**Table 5: Factors increasing the risk of gastrointestinal complications and kidney failure under tNSAR therapy [4]**

### Gastrointestinal complications

- >65/70 years old
- a medical history of ulcer disease (Helicobacter pylori infection)
- a medical history of gastrointestinal bleeding
- further gastrointestinal diseases such as ulcerative colitis or Crohn's disease
- comedication with glucocorticoids, anticoagulants, acetylsalicylic acid (even low dosed) or antidepressants of the selective serotonin reuptake inhibitor (SSRI) type
- stress
- alcohol abuse and dependence
- severe comorbidity

### Kidney failure

- >65/70 years old
- a medical history of kidney disease
- arterial hypertension
- heart failure
- comedication with diuretics or angiotensin-converting enzyme inhibitors
- fluid deficits
- electrolyte imbalance

Recommendation/statement	Grade of recommendation
<b>6-6</b> Traditional nonsteroidal antirheumatics/antiphlogistics should only be used in the lowest efficacious dose and for the shortest possible time.	↑
<b>6-7</b> Do not use traditional nonsteroidal antirheumatics/antiphlogistics parenterally.	↓↓↓

## COX-2 inhibitors

Recommendation/statement	Grade of recommendation
<b>6-8</b> If tNSAR are contraindicated or not tolerated, cyclooxygenase-2 inhibitors may be used in the treatment of acute and chronic nonspecific low back pain (off-label use) with consideration of the safety warnings.	↔

**Caution:** The criteria for off-label use must be taken into account when recommending COX-2 inhibitors in the treatment of low back pain:

- proven efficacy
- favourable risk-benefit profile
- missing alternatives – attempt to cure

If there are no treatment alternatives, off-label drug use is thus only acceptable in the case of severe diseases. There must be a reasonable prospect for treatment success based on the current state of knowledge. Furthermore, there is a special obligation to inform the patient. Off-label use and resulting potential liability must be explained. Decisions must be made jointly.

## Other analgesics

Recommendation/statement	Grade of recommendation
<b>6-9</b> Do not use flupirtine in the treatment of acute or chronic nonspecific low back pain.	↓↓↓

Comment: Although there is no evidence for additional benefits of flupirtine in comparison to other analgesics, attention should be paid to the numerous reports of liver damage under flupirtine and its potential concerning liver toxicity or even total organ failure [21] and reports of suspected flupirtine dependency [22]. As fatigue is very common ( $\geq 10\%$ ), the ability to operate a motor vehicle is impaired. Common (1-10 %) undesired side effects include dizziness, heartburn, nausea/vomiting, stomach discomfort, constipation, sleep disorders, sweating, lack of appetite, depression, tremor, headache, abdominal pain, dry mouth, irritability/nervousness, flatulence and diarrhea [23].

## Opioid analgesics

Recommendation/statement	Grade of recommendation
<b>6-10</b> If analgesics provide insufficient pain relief (paracetamol, tNSAR), weak opioids (e.g. tramadol, tilidine/naloxone) may be used for nonspecific low back pain.	↔
<b>6-11</b> Re-evaluate the opioid therapy after 4 weeks at the latest in the treatment of acute nonspecific low back pain, and after 3 months at the latest in the treatment chronic nonspecific low back pain. If pain and function do not improve as desired, discontinue the opioid therapy.	↑↑↑

Recommendation/statement	Grade of recommendation
<b>6-12</b> To reduce the risk of dependency, slow-acting opioids are to be preferred to fast-acting opioids. Patients should stick to a regular medication schedule ('around the clock'). In general, experimental dose increases that do not provide sustained improvement should be reversed.	Statement
<b>6-13</b> Strong opioids (which are subject to the prescription regulation for narcotics [BTM]) should only be used within a multimodal therapy concept and in cooperation with specialists in pain therapy.	Statement
<b>6-14</b> Do not use transdermal opioids in the treatment of acute or subacute nonspecific low back pain.	↓↓↓

## Muscle relaxants

Recommendation/statement	Grade of recommendation
<b>6-15</b> Muscle relaxants may be used in the treatment of acute and chronic nonspecific low back pain if nondrug measures or non-opioid analgesics alone do not lead to improvements.	↔
<b>6-16</b> Muscle relaxants should be used with care, however, due to side effects such as light-headedness or dependency, allergic effects, reversible impairment of liver function and gastrointestinal complications. They should not be taken for more than 2 weeks continuously in the treatment of acute, subacute and chronic nonspecific low back pain.	Statement
<b>6-17</b> Although benzodiazepine showed pain-relieving effects in clinical studies for nonspecific low back pain, it should be avoided as drugs of this group are highly addictive and its chronic use significantly inhibits active multimodal therapy.	Statement

**Safety warning:** With most myotonolytics, consideration should be given to the risks of sedation and potentially impaired ability to operate a motor vehicle. In addition, there is a risk of dependency, especially with benzodiazepam [24]. In consideration of the side effects, the indication for myotonolytics in treatment of acute and chronic pain must as a rule be critically evaluated and patients should not be treated for more than 2 weeks.

## Antidepressants and other psychopharmaceuticals

Recommendation/statement	Grade of recommendation
<b>6-18</b> Noradrenergic or noradrenergic-serotonergic antidepressants may be considered as additional medication within the scope of an overall treatment concept for pain relief in persons with chronic nonspecific low back pain. In this case, the contraindications and potential side effects must be taken into account.	↔
<b>6-19</b> Antidepressants of the SSNRI type should not be used on a regular basis and only if relevant comorbidity (severe depression, anxiety disorder) justifies its use in persons with nonspecific low back pain.	↓

**Caution:** The criteria for off-label use must be taken into account when recommending psychopharmaceuticals in the treatment of low back pain:

- proven efficacy
- favourable risk-benefit profile
- missing alternatives – attempt to cure

Off-label drug use is thus only permitted in the treatment of severe diseases if there are no treatment alternatives. There must be a reasonable prospect for treatment success based on the current state of knowledge. Furthermore, there is a special obligation to inform the patient. The off-label use and resulting potential liability must be explained. Decisions must be made jointly.

## Antiepileptic medications

Recommendation/statement	Grade of recommendation
<b>6-20</b> Gabapentin, pregabalin and carbamazepine should not be used in the treatment of nonspecific low back pain	↓

## Phytotherapeutics

Recommendation/statement	Grade of recommendation
<b>6-21</b> Phytotherapeutics should not be used in the treatment of acute and chronic nonspecific low back pain.	↓

## Percutaneously administered drugs

Recommendation/statement	Grade of recommendation
<b>6-22</b> Percutaneous medications should not be used in the treatment of acute, subacute and chronic nonspecific low back pain.	↓

## Other intravenously administered drugs

Recommendation/statement	Grade of recommendation
<b>6-23</b> Do not use intravenously or intramuscularly administered pain medications, glucocorticoids and combination infusions in the treatment of acute and chronic nonspecific low back pain.	↓↓↓

## 7. Invasive therapy

No reliable data exist on the use of **percutaneous procedures** in the treatment of acute nonspecific low back pain. Numerous studies have been done on chronic low back pain, but meta-analyses and systemic reviews of these studies have not proven efficacy for any of the procedures in the treatment of nonspecific low back pain.

There are no studies on the use of **surgical procedures** in the treatment of acute or chronic nonspecific low back pain.

Recommendation/statement	Grade of recommendation
<b>7-1</b> Do not use invasive therapeutic procedures in the treatment of patients with nonspecific low back pain.	↓↓↓

## 8. Prevention of low back pain

This chapter is restricted to the three most important and most common preventive approaches: physical activity, education (information/training) and ergonomic measures.

### Physical activity

**Definition:** The term physical activity includes every physical activity that is generated by skeletal muscles and elevates energy expenditure beyond the basal metabolic rate.

Recommendation/statement	Grade of recommendation
<b>8-1</b> Recommend physical activity for the prevention or reduction of low back pain episodes and the prevention of disability.	↑↑
<b>8-2</b> Choose the appropriate procedure depending on the preferences and the condition of the patient.	↑↑

**Comment:** Regular physical activity is more important than the types/methods of activity. Recommendations also cannot be made on the intensity of the physical activity. Although persons with physically demanding jobs are already active, the monotony of these activities puts them even more at risk [25]. In this case, recreational physical activities that balance out work activities will minimise the risk. Health care providers should work closely with the patient to determine which activities would be most appropriate (enjoyment, feasibility, costs, etc.).

### Education (information/training)

**Definition:** Education is understood as involving specific learning processes. Qualified specialists convey health-related knowledge and skills (**health education**). Depending on the aims, education may involve a variety of tasks to improve knowledge and health-promoting habits. Subject matter ranges from simple knowledge transfer (information about the disease in the form of lectures/training, brochures and books) to techniques for behavioural changes. The most important goal of education is to continually motivate the patient to stay physically active.

Recommendation/statement	Grade of recommendation
<b>8-3</b> Information and training concerning the development and progression of low back pain that is based on a biopsychosocial disease concept should be made part of prevention.	↑

### Ergonomics

**Definition:** Ergonomics is concerned with the design of work tasks and work environments, including machines and devices, and the necessary movement sequences. It further concerns job-related education and training on the avoidance of over and under exertion.

When work environments are inspected according to ergonomic principles, the specialist for work safety and the company physician should be involved.

Recommendation/statement	Grade of recommendation
<b>8-4</b> Measures should be taken at the workplace (ergonomic design, behavioural prevention, improvement of job satisfaction) to prevent low back pain.	↑

*Comment:* In view of the great impact of nonspecific low back pain on health care policy and economics, it is regrettable that only a few reputable studies have been carried out so far on prevention. There remains a substantial need here for research, in particular on the sustainability of preventive measures.

## 9. Multimodal, multi- and interdisciplinary treatment/rehabilitation

Multimodal programmes<sup>4</sup> are implemented in Germany in both the curative and rehabilitative sectors.

Recommendation/statement	Grade of recommendation
<b>9-1</b> Treat patients with chronic nonspecific low back pain in multimodal programmes in the curative or rehabilitative sectors if less intensive evidence-based therapies were not sufficient.	↑↑

### Definition

In multimodal treatment and rehabilitation, different modules, that are temporally and substantively coordinated to meet the patient's individual needs, are combined according to a structured interdisciplinary assessment. They consist of medical (pharmacotherapy, education), physical (exercise), work-related and behavioural-therapy components and should be conducted by experts from at least three professional groups with different therapeutic backgrounds (e.g. medicine, physiotherapy/sports therapy, psychotherapy, occupational therapy).

### Aims

The general aims of multimodal treatment are:

- Somatic field:
  - treating pain syndrome/disorder and relieving signs and symptoms, causal intervention and prevention of recurrence
  - reducing pain and pain-related impairments
  - improving physical fitness, muscle power, coordination and mobility
  - improving risk factors and comorbidities (e.g. elevated blood pressure, overweight, lipid disorders, metabolic syndrome, etc.)
  - improving functional abilities
- Psychosocial field:
  - decreasing psychosocial burdens and mental consequences or comorbidities such as depressiveness and anxiety
  - eliminating inadequate coping strategies (e.g. catastrophizing, protective behaviour, persevering behaviour)
  - improving interaction and communication competencies (to avoid instrumental functions of pain behaviour)
  - motivating patients to stay physically active
  - improving mental and social competencies in everyday life and at work

<sup>4</sup> A multimodal treatment/treatment approach program is understood to be a multimodal, multi-, interdisciplinary treatment (ideally in small groups in an integrative setting).

## Scope

Multimodal treatment concepts typically involve multiple professions that come together under an over-arching integrative concept in order to restore functional abilities on different levels. The mainly physically oriented treatment elements still follow the logic of behavioural therapy, putting at the forefront of all treatment efforts the increase of the patient's ability to gain control and sense of competence

The therapeutic elements are:

- medical treatment (e.g. drug therapy, manual therapy)
- intensive information and training on the basis of a biopsychosocial disease model with emphasis on the pain syndrome/disorder and individual problems (e.g. psychosocial risk factors and physical inactivity)
- significant increase in physical activity (e.g. exercise, sports therapy) through motivational and advisory elements regarding daily routine activities, oriented on principles of behavioural therapy as much as possible
- psychotherapeutic treatment measures:
  - to change maladaptive disease behaviour that is directed to rest, sparing oneself or perseverance
  - to strengthen individual capacity for coping with pain and impairment
  - to learn techniques on how to relax, manage stress, cope or (as needed) disorder-oriented individual therapy
- work-oriented training programmes including occupational measures

Relevant comorbidities may also be considered in the therapeutic concept.

## Indications

Multimodal pain therapy within the curative sector is indicated in:

- previously unsuccessful therapy
- change in pain signs and symptoms (increase of pain and adverse effects, also increase of attacks, spreading of signs and symptoms, addition of new pain locations, change of the pain quality; particularly: acute pain decompensation)
- increase in drug consumption (drug withdrawal or repeated drug titration may be necessary)
- psychosocial risk factors contributing to the progression of the disease
- frequent use of medical care
- comorbidities caused by or exacerbating the pain or making therapy difficult
- multimodal therapy within the framework of rehabilitation is indicated if:
  - activity and social participation are impaired due to the disease
  - the ability to work and earn money is seriously at risk or already diminished

These disease aspects falling within the curative sector are likewise important for rehabilitation.

## Initial assessment

Before beginning multimodal therapy programmes, a (structured) multidisciplinary assessment using interdisciplinary diagnostics and patient questionnaires is necessary to validate or dismiss the previously identified medical indication.

Recommendation/statement	Grade of recommendation
<b>9-2</b> Before the multimodal treatment of chronic nonspecific low back pain, perform a structured assessment <sup>5</sup> and follow up with a team consultation for creating a therapy plan.	↑↑

## Criteria for assigning multimodal treatment to patients

Recommendation/statement	Grade of recommendation
<b>9-3</b> If the patient is at risk for chronification ('yellow flags'), consider the indication for multimodal therapy (ideally through a comprehensive interdisciplinary assessment <sup>5</sup> ), at the latest after 6 weeks of continuous pain and limitations in daily routine activities <sup>6</sup> despite guideline-compliant medical care.	↑↑
<b>9-4</b> If complaints persist and limitations in daily routine activities are present >12 weeks despite guideline-compliant medical care, always test whether multimodal therapy is indicated (where possible through a comprehensive interdisciplinary assessment).	↑↑

## Access

Access to multimodal treatment is granted by the responsible physician, who prescribes inpatient, part-time inpatient or outpatient treatment (reimbursed by the National Association of Statutory Health Insurance Physicians).

In the rehabilitative care sector, the insured person must submit a claim form to the provider of rehabilitation benefits (normally the German Statutory Pension Insurance Scheme [RV rehabilitation application form] or the National Association of Statutory Health Insurance Physicians [KV Form 60, Form 61]). Rehabilitative care is provided in specialised outpatient or inpatient rehabilitation centres.

## Post-rehabilitation support

Post-rehabilitation support after multimodal treatment in both the curative and the rehabilitative sectors seeks to achieve two different primary aims [26; 27]:

- Stabilising individual behavioural and decision-making competencies in coping with low back pain and low back pain episodes and in the prevention of recurrent low back pain.
- Continuation of physical/physiotherapeutic activity to improve health-related fitness.

<sup>5</sup> A multidisciplinary assessment would be ideal, but local conditions sometimes only allow interdisciplinary exchange.

<sup>6</sup> 'Limitations in daily routine activities' is defined according to the individual situation of the person concerned, e.g. the inability to work for employees or the inability to perform normal tasks or activities for the unemployed.

Recommendation/statement	Grade of recommendation
<b>9-5</b> Preparation for the period after treatment (e.g. self-dependent physical activity, sports, etc.) must be an integral part of the therapy plan. The primary goal is the transition from therapy compliance to activities performed through individual initiative.	↑↑
<b>9-6</b> Commence additional therapeutic measures according to the recommendations in the final report or after a reassessment. <sup>7</sup>	↑↑
<b>9-7</b> All patients should be advised on opportunities to join self-help groups that promote proactive behaviour and personal responsibility.	↑
<b>9-8</b> After multimodal therapy programmes in the curative sector, short follow-up treatments may be performed.	↔
<b>9-9</b> Follow-up treatment measures should be offered to the patient if the treatment benefits have not been sufficiently maintained after rehabilitation.	↑

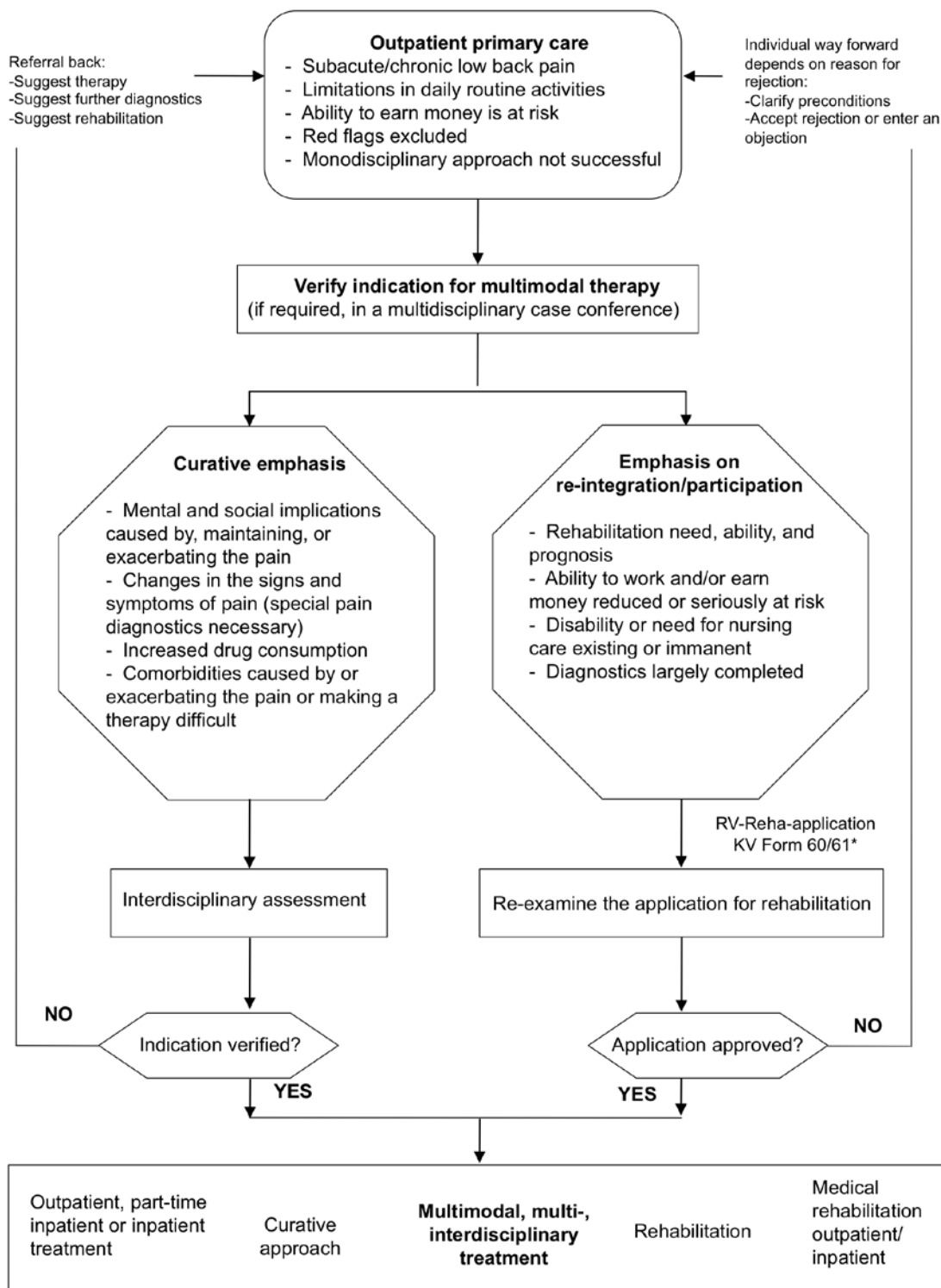
## Re-integration into employment for nonspecific low back pain

The re-integration of patients into the workforce is an important treatment goal in the case of nonspecific low back pain.

The type and extent of the step-wise re-integration depend on different criteria such as the work's complexity, scope, feasibility, etc. and is ideally coordinated between the patient, the company physician and the company.

Recommendation/statement	Grade of recommendation
<b>9-10</b> Consider and, where needed, initiate measures in both the rehabilitative and the curative sectors for promoting professional re-integration.	↑↑

<sup>7</sup> The assessment should be multidisciplinary; local conditions, however, sometimes only allow interdisciplinary exchange.



\* Notes on the legislative context in the Appendix.

Algorithm 1: Suggested procedural flow for patients with nonspecific low back pain

## 10. Care coordination

Depending on the patient's individual problems, risks and preferences (primary care is also provided in part by the specialist), there are three levels of care:

1. general/primary care treatment
2. outpatient specialist treatment
3. specific specialist treatment in centres, hospitals, rehabilitation centres (outpatient/inpatient).

The main care provider must accordingly coordinate the care activities and manage the interfaces between the levels (tutoring), keeping in mind the patient's preferences. The latter requires that the patient be sufficiently informed about the disease. Shared decision-making is an essential part of a good physician-patient relationship [28].

Recommendation/statement	Grade of recommendation
<b>10-1</b> A physician is to take on the 'tutor role' for the entire care process. He/she is the primary contact for the patient and coordinates all treatment steps.	↑↑

### Care coordination for acute low back pain

Depending on individual preferences, the patient may choose for the first consultation either the primary care sector (in the fields of internal medicine and general medicine or internal medicine without subspecialisation, physicians without field designation) or specialist offices for orthopaedics and trauma surgery or physical and rehabilitative medicine.

#### Initial diagnostics

The first diagnostic assessment comprises the medical history evaluation and the clinical examination. A thorough medical history record encompasses biological, mental and social aspects. This allows for a preliminary estimation of the risk for chronification (yellow flags) to already be made at this time (see Algorithm 2).

If there are specific warning signs of preventable serious illness (red flags) in the results, a referral may be considered appropriate to clarify the aetiology and treat the disease. Depending on the medical history and clinical findings, relevant specialists may be consulted.

Recommendation/statement	Grade of recommendation
<b>10-2</b> Complaints in the instance of acute, nonspecific low back pain are usually self-limiting (see Chapter H1). The majority of persons seeking medical consultation for the first time because of low back pain thus only require advice and acute care.	<b>Statement</b>

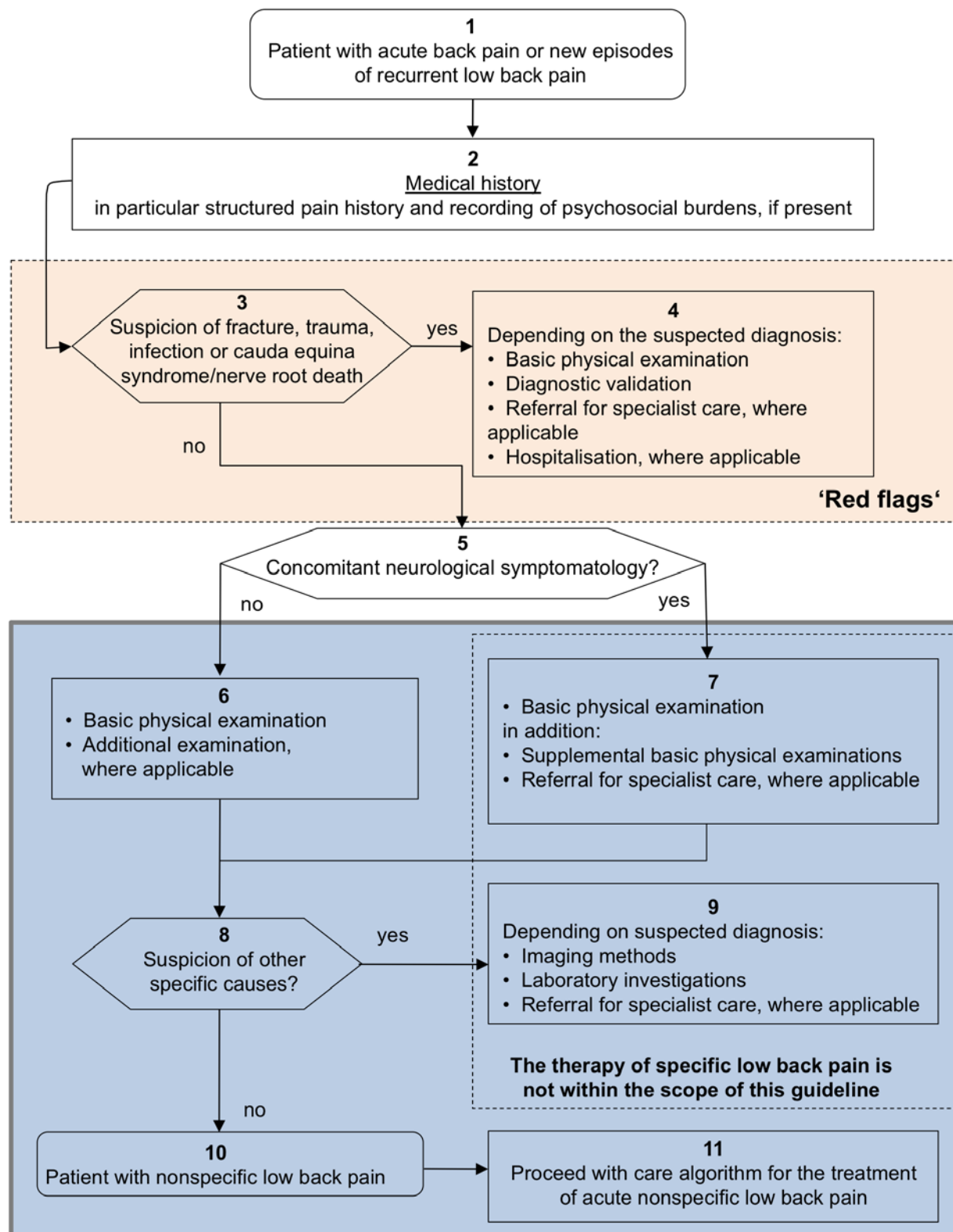
#### Acute care

If the first diagnosis does not result in suspicion of any specific causes of the pain, a symptomatic therapy may be performed. Besides the **drugs taken for pain, additional therapies may be applied** already in the acute stage, where appropriate. **Educating the patient** at this time about his/her condition is especially important. Patients should certainly stay physically active, if possible. During the first preventive consultation, they should be informed that sparing oneself physically is counterproductive in the treatment of nonspecific low back pain and considerably reduces the chance of recovery.

If the therapy does not produce the desired effects after 2-4 weeks of acute treatment, the risk factors for chronification (yellow flags) should be systematically recorded (see Algorithm 3).

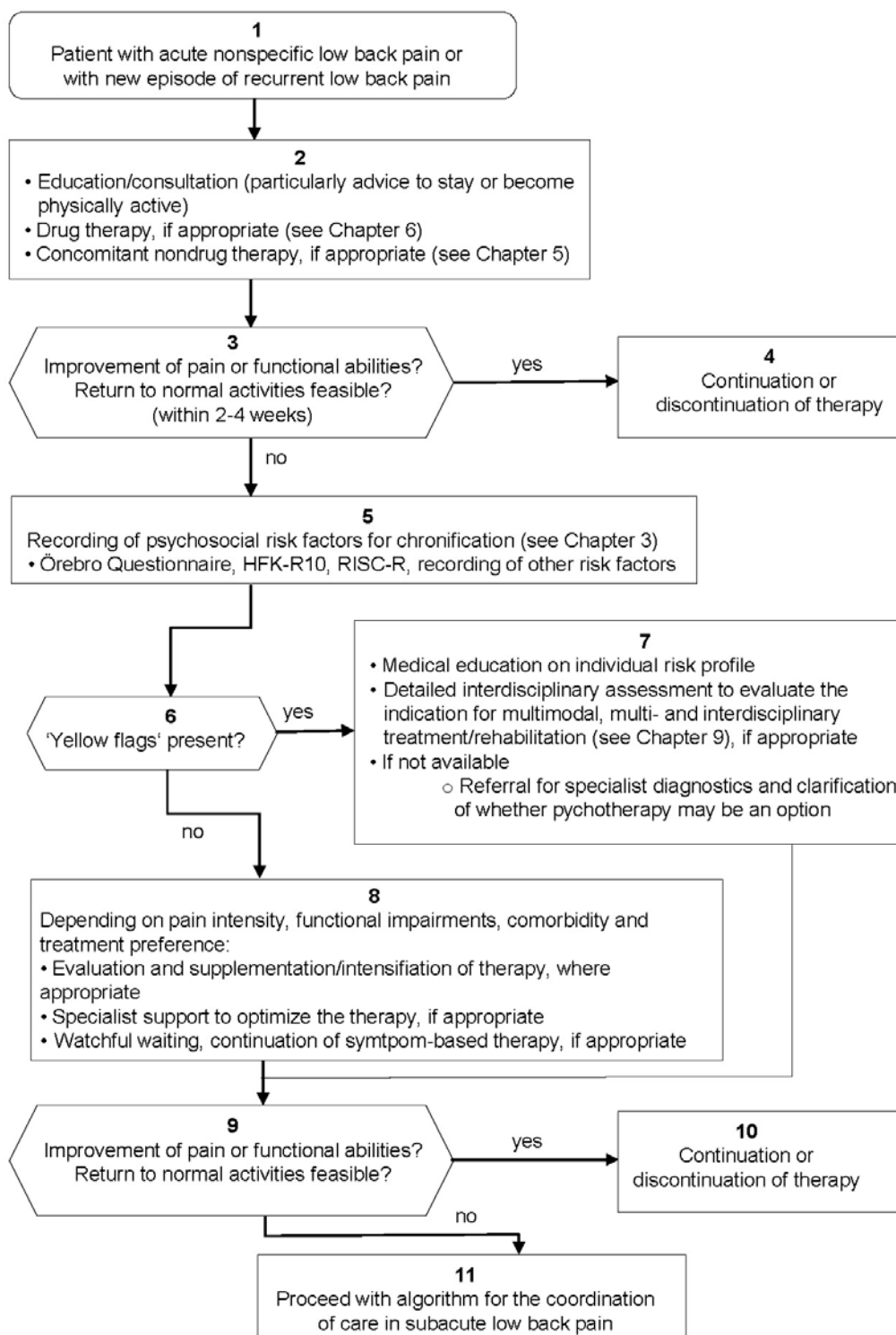
Recommendation/statement	Grade of recommendation
<b>10-3</b> If there is a suspicion of psychosocial burdens in the instance of unspecific low back pain persisting for 2 weeks, medical or psychological psychotherapists may be consulted for further diagnostics and treatment after medical consultation.	$\Leftrightarrow$

Comment: If psychotherapy is not indicated, the therapist may instead simply give recommendations on how to communicate with the patient or how to continue treatment within the framework of basic care.



Algorithm 2: Diagnostics of 'red flags' and specific causes (0-2 weeks after first consultation)

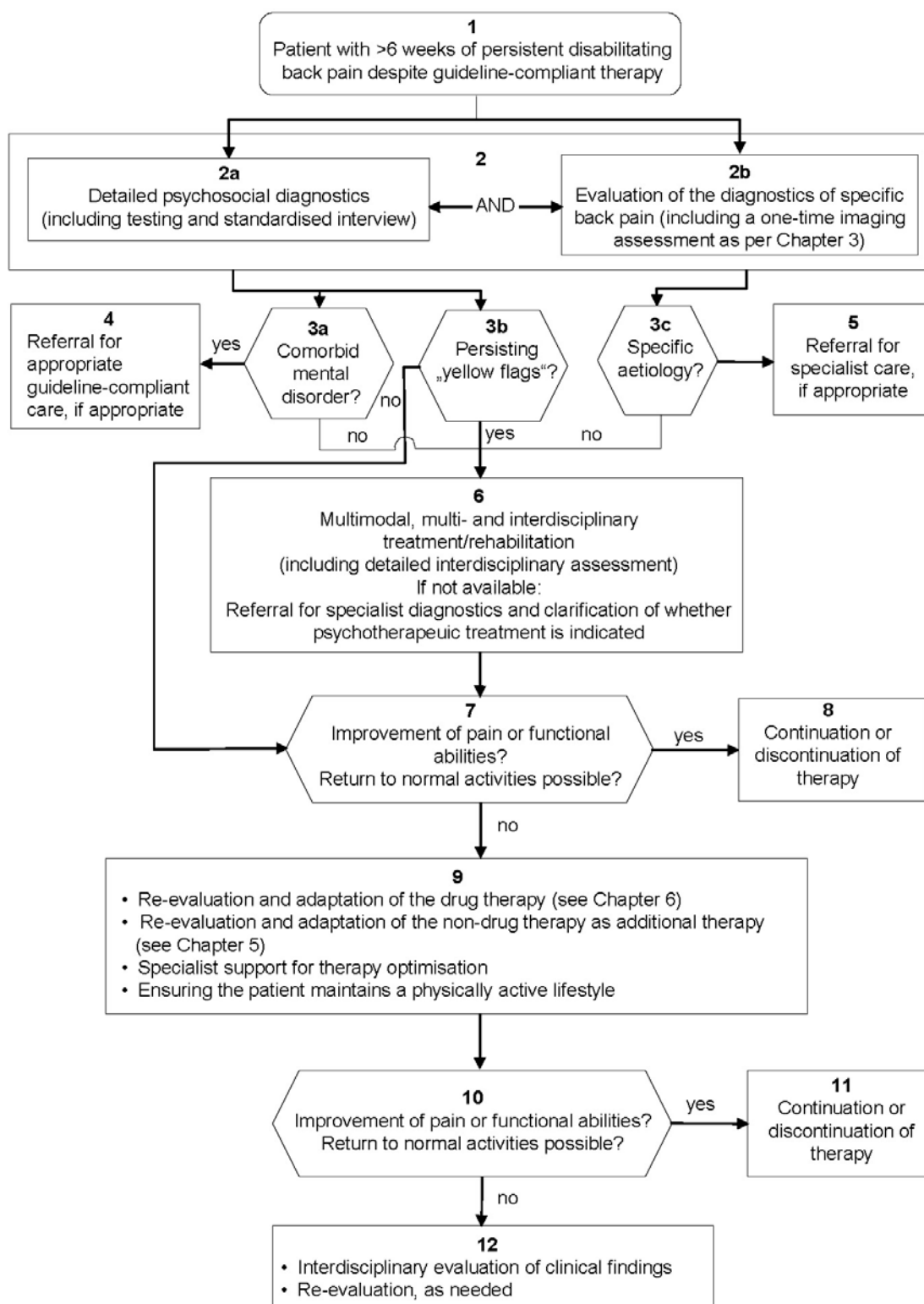
Recommendation/statement	Grade of recommendation
<b>10-4</b> During treatment, symptom-based basic therapy is continued, evaluated and, where applicable, supplemented/intensified (see Chapter H 6). Primary care providers should consider involving other specialist disciplines, particularly if the patient remains unable to work for more than 2 weeks.	↑



**Algorithm 3: Further diagnostics and therapy in acute nonspecific low back pain (2-5 weeks after first consultation)**

## Care coordination of subacute low back pain

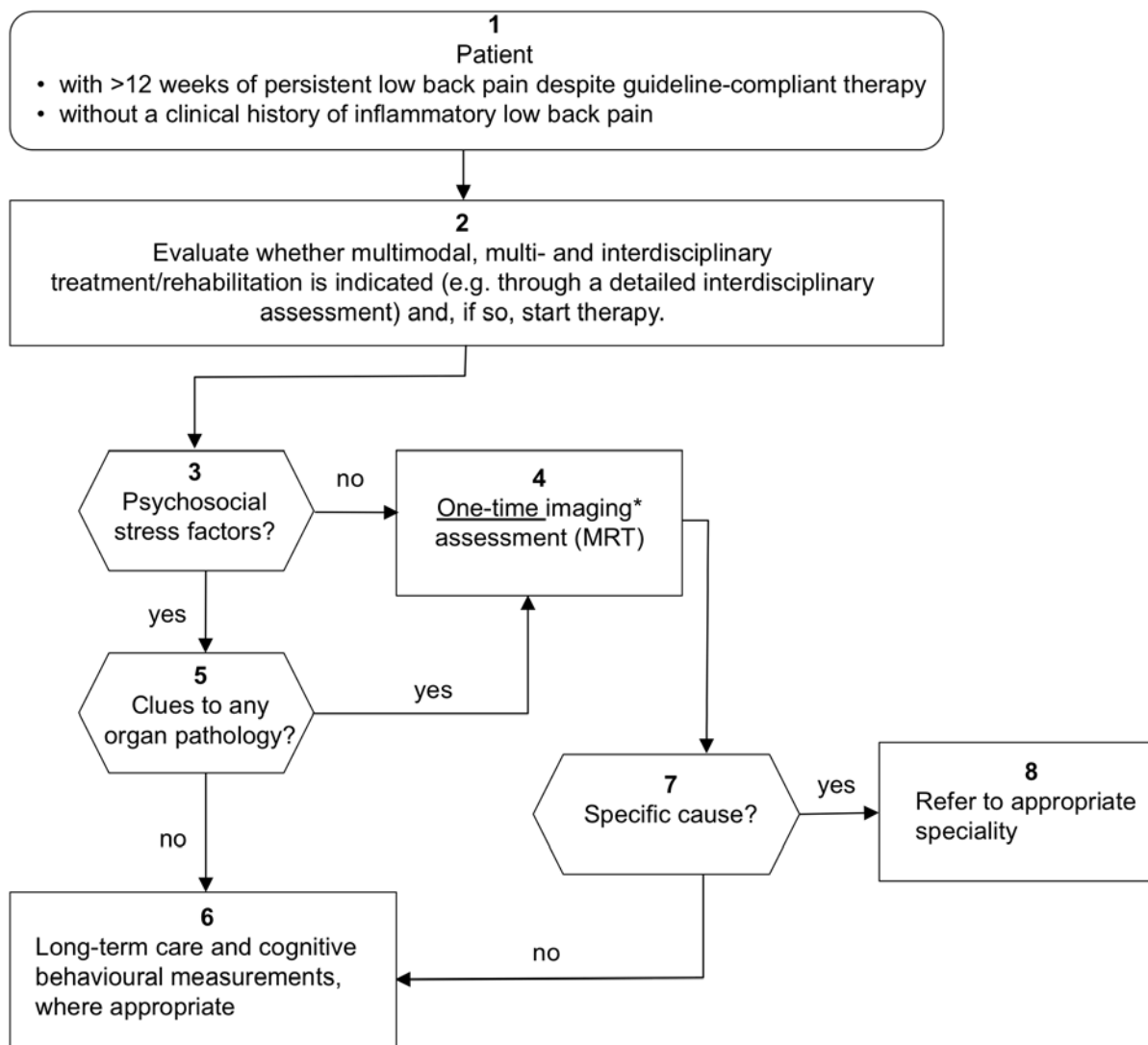
Recommendation/statement	Grade of recommendation
<b>10-5</b> If pain persists for 6 weeks, redo diagnostics for acute low back pain (see Chapter H 3) to validate the first diagnosis. Check for the presence of 'yellow flags' or 'red flags'.	↑↑
<b>10-6</b> In the case of (comorbid) mental disorders, take measures for adequate guideline-compliant medical care.	↑↑
<b>10-7</b> If activity-limiting low back pain persists despite guideline-compliant therapy (subacute low back pain), compile available clinical signs and symptoms across all disciplines and evaluate them jointly at a case conference after 6 weeks of pain at the latest.	↑↑
<b>10-8</b> If there are still no risk factors for chronification in the subacute stage, the treatment emphasis is to be on the optimisation of symptomatic therapy.	↑↑



Algorithm 4: Medical care for subacute low back pain (6-12 weeks after first consultation)

## Care coordination in chronic nonspecific low back pain

Recommendation/statement	Grade of recommendation
<b>10-9</b> If assessments do not reveal any specific findings by 12 weeks, the diagnosis will probably be chronic nonspecific low back pain.	<b>Statement</b>



\* only under the condition that no imaging technique was used by 6 weeks

**Algorithm 5: Medical care in the transition to chronic nonspecific low back pain (>12 weeks after first consultation)**

Recommendation/statement	Grade of recommendation
<b>10-10</b> During the course of the disease emphasis is placed on constant education and encouraging a healthy lifestyle which includes regular physical activity and the avoidance of medical procedures that promote chronification and/or are not based on scientific evidence.	<b>Statement</b>

Table 6: Long-term care measures

Long-term care	
<ul style="list-style-type: none"> <li>Educate continuously and encourage a healthy lifestyle which includes regular physical activity</li> <li>Avoid medical procedures promoting chronification</li> </ul>	
Clinical situation	Actions required
<b>Change in clinical picture</b>	<ul style="list-style-type: none"> <li>Educate and give advice</li> <li>Evaluate diagnostic measures and therapeutic interventions in view of the clinical findings</li> </ul>
<b>Intake of drugs for pain &gt;4 weeks</b>	Regular monitoring of: <ul style="list-style-type: none"> <li>Need for continuing the therapy (see Chapter H 6)</li> <li>Undesired side effects</li> <li>Drug-drug interactions</li> <li>Adequate dosing</li> <li>Use of appropriate nondrug measures, e.g. psychosocial interventions</li> <li>Need for clarification/control of existing or new comorbidities by a specialist</li> <li>Need for a specific pain-therapeutic or rehabilitative measure</li> <li>Need for social-legal advice</li> </ul>
<b>Discharge from outpatient/inpatient pain-therapeutic intervention or rehabilitation</b>	<ul style="list-style-type: none"> <li>Evaluate adequacy and practicability of the recommended therapeutic measures</li> <li>Help with the implementation and coordination of measures</li> <li>Monitor compliance to regimen (e.g. sports or functional exercise)</li> <li>Stepwise return to work</li> <li>Initiate and coordinate further psychotherapeutic treatment, if needed</li> <li>Coordinate continued specialist treatment, if needed</li> <li>Provide support and cooperate with follow-up care programmes (see Chapter H 9), if needed</li> <li>Watch the social-legal situation, where needed</li> </ul>
<b>Continued existence of risk factors and/or proven psychosocial consequences of low back pain</b>	<ul style="list-style-type: none"> <li>Appointments according to fixed treatment schedule/consultation, as needed only in case of emergency</li> <li>Basic psychosomatic care</li> <li>Initiate and coordinate continuing psychotherapeutic treatment, if needed</li> <li>Social-legal advice or initiating it, as applicable</li> </ul>
<b>Comorbidities maintaining or intensifying the symptoms</b> (e.g. affective disorders such as anxiety, depression or somatoform disorders)	<ul style="list-style-type: none"> <li>Fixed treatment schedule/consultation, as needed only in case of emergency</li> <li>Basic psychosomatic care</li> <li>Initiate and coordinate treatment of the comorbidity</li> </ul>

## 11. Quality requirements, quality management and implementation of the guideline

Physicians are obligated by laws governing the exercise of the profession and social law to maintain quality assurance and promote professional development. They must therefore respect the basic principles of correct medical practice constituted in the code of medical ethics.

### Quality indicators

Based on recommendations, the National Disease Management Guidelines present preliminary methodologically proven quality indicators for relevant preventive, diagnostic and therapeutic measures or interfaces. Quality indicators help to determine whether disease-specific care is being carried out according to the guidelines or whether care can be improved at certain points.

As the assessment was done without data, the following indicators have been methodologically verified in the interim. For use in practice, additional specifications are needed such as the acquisition period or the required survey data with respect to specific data fields. The indicators were defined without naming an actual area of application. Before being widely introduced into practice, indicators must be fully evaluated after the administration of a pilot test for validation.

**Table 7: Proposals for quality indicators for the care of persons with nonspecific low back pain**

Indicator	Derived from	Specifications in this guideline
<b>Diagnostics</b>		
<b>1. Psychological risk factors and instruments for early detection</b> <b>Numerator:</b> Number of patients systematically assessed for psychosocial risk factors <b>Denominator:</b> All patients with persisting nonspecific low back pain after 4 weeks of guideline-compliant measures	<ul style="list-style-type: none"> <li>Recommendation 3-2</li> <li>Goal 4</li> </ul>	Psychosocial factors ('yellow flags'): see Chapter H 3.2.2 and Appendix 2 and 3
<b>Additional remarks:</b> The risk may need to be adjusted in persons with migration background (speech barriers). <b>Potential barriers requiring attention during implementation:</b> <ul style="list-style-type: none"> <li>Low acceptance because interpretation of evidence is different</li> <li>Ignorance of the instruments</li> <li>Lack of time</li> <li>Lack of reimbursement</li> <li>Lack of resources (personnel, working materials)</li> </ul>		
<b>2. Imaging methods for acute low back pain</b> <b>Numerator:</b> Number of patients not scheduled for imaging <b>Denominator:</b> All patients with acute low back pain and without any signs of 'red flags' concerning medical history and clinical assessments	<ul style="list-style-type: none"> <li>Recommendation 3-5</li> <li>Goal 7</li> </ul>	Medical history, definition of 'red flags' see Chapter H 3.2, physical examination: see Chapter H 3.3
<b>Potential barriers requiring attention during implementation:</b> <ul style="list-style-type: none"> <li>Incompatibility with patient preferences</li> <li>Not cost-effective (here: lack of economic incentive)</li> <li>Risk of legal consequences</li> </ul>		
<b>Nondrug therapy of nonspecific low back pain</b>		
<b>3. Physical activity and exercise</b> <b>Numerator:</b> Number of patients advised to stay as active as possible <b>Denominator:</b> All patients with acute nonspecific low back pain (0-6 weeks)	<ul style="list-style-type: none"> <li>Recommendation 5-5</li> <li>Goal 9</li> </ul>	No prescription of specific exercise: see Recommendation 5-6
<b>Potential barriers requiring attention during implementation:</b> <ul style="list-style-type: none"> <li>Incompatibility with patient preferences</li> </ul>		
<b>Drug therapy of low back pain</b>		

Indicator	Derived from	Specifications in this guideline
<b>4. Opioid analgesics</b> <b>Numerator:</b> Number of patients whose opioid therapy was re-evaluated after 3 months at the latest <b>Denominator:</b> All patients with chronic low back pain and 3 months of continuous opioid therapy	<ul style="list-style-type: none"> <li>Recommendation 6-11</li> <li>Goal 8</li> </ul>	Priority given to prescribing weak opioids with slow onset of action: see Chapter H 6.2
<b>Potential barriers requiring attention during implementation:</b> <ul style="list-style-type: none"> <li>Lack of time</li> <li>Lack of reimbursement</li> <li>Lack of resources (personnel, working material)</li> </ul>		
<b>5. Opioid analgesics</b> <b>Numerator:</b> Number of patients receiving transdermal opioids <b>Denominator:</b> All patients with acute (0-6 weeks) and subacute (6-12 weeks) low back pain	<ul style="list-style-type: none"> <li>Recommendation 6-14</li> <li>Goal 12</li> </ul>	Further information on opioids that are subject to the prescription regulation for narcotics: see Chapter H 6.2 and Statement 6-13 Actor: multi-/interdisciplinary treatment team
<b>Additional remarks:</b> Although the recommendation is expressed negatively, the quality indicator is expressed positively. The target value should be as low as possible.		
<b>Potential barriers requiring attention during implementation:</b> <ul style="list-style-type: none"> <li>Incompatibility with patient preferences</li> </ul>		
<b>6. Other intravenous drugs</b> <b>Numerator:</b> Number of patients receiving intravenous or intramuscular drugs, glucocorticoids and combination infusions <b>Denominator:</b> All patients with nonspecific low back pain	<ul style="list-style-type: none"> <li>Recommendation 6-23</li> <li>Goal 12</li> </ul>	
<b>Additional remarks:</b> Although the recommendation is expressed negatively, the quality indicator is expressed positively. The value should be as low as possible.		
<b>Potential barriers requiring attention during implementation:</b> <ul style="list-style-type: none"> <li>Incompatibility with patient preferences</li> <li>Not cost-effective (here: lack of economic incentive)</li> </ul>		
<b>Invasive therapy</b>		
<b>7. Invasive therapies</b> <b>Numerator:</b> Number of patients receiving invasive therapy <b>Denominator:</b> All patients with nonspecific low back pain	<ul style="list-style-type: none"> <li>Recommendation 7-1</li> <li>Goal 9</li> </ul>	Percutaneous and surgical procedures: see Chapter H 7 and Appendix 6 and 7
<b>Additional remarks:</b> Although the recommendation is expressed negatively, the numerator is expressed as positive quantity. The targeted value should as low as possible.		
<b>Potential barriers requiring attention during implementation:</b> <ul style="list-style-type: none"> <li>Incompatibility with patient preferences</li> <li>Not cost-effective (here: lack of economic incentive)</li> </ul>		
<b>Multimodal, multi- and interdisciplinary treatment/ rehabilitation</b>		
<b>8. Multimodal, multi- and interdisciplinary treatment/ rehabilitation</b> <b>Numerator:</b> Number of patients treated in a multimodal, multi- and interdisciplinary programme/ rehabilitation <b>Denominator:</b> All patients with chronic (>12 weeks) nonspecific low back pain and insufficient response to less intensive therapies	<ul style="list-style-type: none"> <li>Recommendation 9-1</li> <li>Goal 11</li> </ul>	Definition multimodal, multi- and interdisciplinary programmes/ rehabilitation: see Chapter H 9.1 Actor: multi-/interdisciplinary treatment team

Indicator	Derived from	Specifications in this guideline
<b>Additional remarks:</b> Before pilot testing, 'insufficient response to therapy' and the time intervals for measurement must be defined.		
<b>Potential barriers requiring attention during implementation:</b> <ul style="list-style-type: none"> <li>• Insufficient access to/ insufficient availability of health care services</li> <li>• Lack of time</li> <li>• Not cost-effective (here: high costs)</li> <li>• Recommendation cannot be communicated due to definition problems</li> </ul>		
<b>9.</b> <b>Numerator:</b> Number of patients tested for the indication for multimodal therapy (through comprehensive interdisciplinary assessment) <b>Denominator:</b> All patients with chronic (>12 weeks) nonspecific low back pain and limitations in daily routine activities despite guideline-compliant care	<ul style="list-style-type: none"> <li>• Recommendation 9-4</li> <li>• Goal 11</li> </ul>	Definition 'limitations in daily routine activities' and 'comprehensive interdisciplinary assessment': see Chapter H 9.4.1 and H 9.4.2 Actor: multi-/ interdisciplinary treatment team
<b>Additional remarks:</b> The phrase 'ideally through comprehensive interdisciplinary assessment' reflects the currently absent nation-wide availability of interdisciplinary assessments. For use as a quality indicator, 'ideally' was deleted.		
<b>Potential barriers requiring attention during implementation:</b> <ul style="list-style-type: none"> <li>• Insufficient access to/ insufficient availability of health care services</li> </ul>		

## Appendix 1: Selection of sources and derivation of recommendations

For preparation of the NDMG 'low back pain', a systematic guideline search was performed which updated the search for the clearing reports 'acute back pain' [29] and 'chronic back pain' [30].

The identified guidelines were then subjected to a structured methodological evaluation using the German instrument for the methodological evaluation of guidelines (DELBI) [31]. Based on the evaluation outcome, the guideline-group opted for the following source guidelines:

- German College of General Practitioners and Family Physicians (DEGAM): Kreuzschmerz. 2003 [9].\*
- Drug Commission of the German Medical Association: Empfehlungen zur Therapie von Kreuzschmerzen. 3rd edition. 2007 [4].
- Spine Society of Europe: European guidelines for prevention in low back pain. 2004 [33].
- Spine Society of Europe: European guidelines for the management of acute nonspecific low back pain in primary care. 2005 [10].
- Spine Society of Europe: European guidelines for the management of chronic non-specific low back pain. 2005 [34].

A systematic development of the recommendations and an underlying comprehensible evidence-based approach were crucial for the decision-making process.

Supplemental **systematic searches** for other sources of evidence (e.g. HTA reports and systematic reviews) and **primary studies** were performed for topics not sufficiently covered in the source guidelines as well as for updating purposes. The guideline-group identified a special need for additional information in the fields of **prevention** and individual **nondrug therapy forms**. It should however be noted that after the studies scientific evidence remains insufficient in many areas and/or is inconsistent and recommendations can often only be derived to a limited extent.

The recommendations of this guideline are based on the source guidelines or on the results of systematic searches (see guideline report). If the guideline group regarded specific topics as important, but recommendations could not be based on published evidence due to missing studies, the recommendations rely on expert opinion. The guideline report of this NDMG gives a concise overview of the sources of each recommendation.

This NDMG has adopted the GRADE approach for grading recommendations [35; 36], as described in the current Method Report for the NDMG programme [37].

**Table 8: Grading of guideline recommendations**

Grade of recommendation	Meaning	Wording	Symbol
A	Strong recommendation	'Do'	☐☐
		'Do not'	☐☐
B	Recommendation	'Should do'	☐
		'Should not do'	☐
O	Open	'May do'	☐

\* There is an update that compares the DEGAM-LL with the European guidelines and the guidelines of the Drug Commission of the German Medical Association [32].

In general, the level of evidence should be determinative for the recommendation grade. Moderate evidence should therefore lead to a moderate recommendation grade. The grading of recommendations also takes account of:

- Ethical obligations
- Clinical relevance of the efficacy measures in the study
- Applicability of the study results to the patient target population
- Patient preferences
- Practicability in physicians' everyday work [38]

Based on these consensus aspects, a justified up- or downgrading of recommendation grades relative to the evidence level may occur. Often recommendations had to be made on the basis of trade-offs between risks and benefits owing to insufficient and/or contradictory evidence. Individual explanations are given as comments below the respective recommendations. Expert opinions were also brought into alignment and jointly phrased during the formalised consensus process.

**The NDMG methodology provides that the grading of recommendations by the guideline group follows a formal consensus development procedure.**

According to this requirement, a multi-part nominal group process was used [39-41] that was moderated by either Frau Prof. Kopp (*AWMF*) or Herr Prof. Ollenschläger (*AQuMed*). The participants in this procedure were designated representatives of different medical specialties and organisations that were involved in the development of the guideline. Each association/organisation had one vote in the voting procedure. The results of the votes were made available to the whole body of experts immediately after each meeting.

The procedure was conducted in six steps:

- silent review of the guideline manuscript
- opportunity to make notes to the key recommendations and the proposed graduation
- moderator records the judgements and alternative proposals for each recommendation in a single rating round; in doing so, verbal input is provided only for clarification purposes
- preliminary voting on all recommendation grades and the proposed alternatives
- discussion of matters on which the participants were unable to reach strong consensus in the first round
- final vote

**Table 9: Topics of the structured consensus procedure**

Chapter		Moderation	Date	Voting societies/ organisations
Chapter 3:	Diagnostics	Frau Prof. Kopp (AWMF)	28.09.2009	DGAI, DGN, DEGAM, DGR, AkdÄ, DGRW, DGOOC, DGSMP, DGMM, DGIM, DGSS, DGNC, DGPM, DGPMR, DGNR (n = 15)
Chapter 5,7,8,9:	Nondrug therapy, invasive therapy, prevention, multimodal therapy/ rehabilitation	Frau Prof. Kopp (AWMF)	29.09.2009	DGAI, DGN, DEGAM, ZVK, DGR, AkdÄ, DVE, DGRW, DGOOC, DGPM, DGSMP, DGPMR, DGMM, DGSS, DGRh, DGNR, DGNC, DGU (n = 18)
Chapter 10:	Care coordination	Frau Prof. Kopp (AWMF)	23.11.2009	DGAI, DGN, DEGAM, ZVK, DGR, AkdÄ, DVE, DGRW, DGOOC, DGSMP, DGMM, DGIM, DGSS, DGNC, DGPM, DGPMR, DGNR, DGPT, DGIM (n = 19)
Chapter 6:	Drug therapy			DGAI, DGN, DEGAM, DGR, AkdÄ, DGRW, DGOOC, DGSMP, DGMM, DGIM, DGSS, DGNC, DGPM, DGPMR, DGNR, DGPT, DGIM (n = 17)
Chapter 6:	Drug therapy	Herr Prof. Ollenschläger (AQuMed)	15.03.2010	DGAI, DEGAM, DGPT, AkdÄ, DGOOC, DGSMP, DGSS (n = 7)

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German Radiology Society (DRG)

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