



UEMS PRM Section & Board

Clinical Affairs Committee

New accreditation procedure

Programme n°3

PRM and patients suffering from low back pain with lumbosacral radiculopathy

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Comments of the Clinical Affairs Committee

The programme fits the European accreditation standards.

Although the official title is “PRM Programme for patients with Low Back Pain with lumbar roots neuropathy”, this programme is mainly focused on Low Back Pain. Radiculopathy rather appears as an inclusion criterion, than a core issue of the programme.

The programme is consistent with current International recommendations. However, the committee agrees with the author on that scientific evidence is still lacking about the efficiency of some physical modalities, which are traditionally used against LBP. Event though, low evidence doesn't mean “evidence against” those modalities (see: “General principles of the programme”). Additional information about this issue will be added to the eBook, with respect to forthcoming scientific data.

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II. Summary

2 **Background:** The Programme is performed in the out-patient rehabilitation department, which
3 is part of the PRM and Sports Medicine Centre in the University Hospital. The organization of
4 the Programme is based on: National Regulation, on the White Book on Physical and
5 Rehabilitation Medicine in Europe, and on International scientific guidelines and
6 recommendations.

7 **Target population and procedure:** The Programme is focused on adult patients of any
8 gender and age, suffering from low back pain combined with lumbosacral radiculopathy,
9 causing person's moving or self-care impairment, at any phase of its development: acute, sub-
10 acute or chronic. Patients are referred to our Department directly by their GPs or by other
11 consultants. The Programme is funded by the National Health Insurance. Safety and patient
12 rights are defined by National regulations. Each patient signs an informed consent.

13 **The main goals of the Programme** are: to relieve pain, to improve patient's functioning and
14 activity, to enable participation, to reduce sick-leaves duration and working absenteeism, to
15 prevent pain recurrence and chronic evolution.

16 **The Department permanent manpower** consists of 2 PRM specialists, 4 physiotherapists, 1
17 occupational therapist, 1 psychologist, 1 social worker, 4 nurses, 3 massage specialists. Other
18 professionals may contribute to the Programme on demand. The Department is **equipped** with
19 a wide range of facilities, which include: 3 consultation rooms, 4 exercise rooms, one is
20 equipped with spinal traction system, 2 pools (one with spinal traction equipment), 4 rooms of
21 physical modalities, 3 massage rooms one room for acupuncture procedures and manual
22 therapy procedures, some space designed for patients rest; Different imaging techniques (X-
23 rays, CT, MRI, ultrasound imaging and others) are available in the Hospital.

24 **The approach to the Programme is multi-professional.** The PRM specialist has an overall
25 leadership on the team and is "the patient's manager". He/she is responsible for the initial
26 patient's evaluation, the set up of an appropriate strategy, the team coordination and further
27 patient's follow-up.

28 **Patient's assessment** is based on the evaluation presented in the White Book on Physical
29 and Rehabilitation Medicine in Europe, appendix IV and suggested in International guidelines.
30 The members of the team evaluate the patient subsequently. On the basis of this
31 comprehensive evaluation, the initial PRM strategy is adjusted and the rehabilitation plan is
32 confirmed. It may be adapted according to patient's clinical and functional findings, after
33 regular team meetings.

34 **Treatment methods** to relieve pain consist of physical modalities (especially electrotherapy
35 and ultrasounds), massage and tractions in pool. Coping with pain is favoured by
36 psychotherapy and relaxation. In order to enhance functioning abilities, we use exercises in
37 pools, exercise therapy (individual and in groups). Return to work and prevention are based on
38 effort training, consultations for working place adjustments and ergonomics.

39 All patient's medical and functional information, assessment and further monitoring data is
40 recorded manually into a **standardised medical documentation**. A standardised discharge
41 report with further recommendations is written in several copies, for the patient and for his/her
42 GP. All the Programme documents are stored in the clinical archive and are accessible for
43 periodic internal or external audit and outcomes assessment.

44 **Long term outcomes monitoring** of our patients has been started recently and the data
45 analysis is in progress. These efforts should contribute to a quality improvement approach of
46 our programme in the following years.

III. General bases of the Programme

A. PATHOLOGICAL AND IMPAIRMENT CONSIDERATIONS

1. *Aetiology, pathogeny and prognosis*

a) Low back pain

“**More than 99% of low back problems present with back pain** and it is rare to see a low back problem with no back pain. Pain always tends to radiate distally and 70% of patients with back pain also have some pain down one or both legs. **Neurologic symptoms** and spinal deformity are much less common but **crucial to diagnosis**.” (Gordon Waddell) (A.1).

In the scientific literature, three types of low back pain (LBP) are used in patients triage (A.2, A.3):

- 1) non-specific low back pain – up to 90% of all LBP;
- 2) back pain with neurological involvement – nerve root affection;
- 3) back pain with suspected serious spinal pathology (“red flags”).

All anatomic structures (i.e. intervertebral disc, posterior joints, ligaments and muscles) may contribute to non-specific LBP, with or without neurological involvement (A.4). Intervertebral disc degeneration with vertebral plateau oedema is a condition for prolonged subacute lumbar pain (Modic I signal on MRI) (A.5, A.6).

However, imaging information has a poor predictive value of chronic LBP (A.7, A.8). Functional desadaptation, sociopsychological factors (fears, beliefs and avoidances) (A.9) and even genetics (A.10, A.11, A.12) hold an important place in the determinism of chronic pain evolution. Understanding them better helps to define the main targets of PRM programmes, even though establishing the prognosis of LBP remains very difficult.

b) Lumbosacral radiculopathy

In accordance with our National regulations (B.1), we focus on LBP with lumbosacral radiculopathy caused by degenerative process: herniated lumbar disc, spondylosis, spinal stenosis.

LBP with lumbosacral radiculopathy of organic or traumatic origin is not considered in this programme. Serious spinal pathology, such as cancer, infection, inflammatory spondyloarthritis, trauma (i.e. “red flags”), is excluded since it requires specific treatment.

Root compression cannot fully explain the radicular pain. Inflammatory factors released by the degenerated disc are aggressive against the nerve root, even without anatomic compression. Local oedema has also been recognized as a cause of pain. This explains the efficiency of general and local treatments with inflammatory drugs (A.11, A.12).

Radicular pain may disappear even though a disc herniation will sometimes persist for years. The risk of recurrence is not higher after medical treatment than after surgical decompression. Furthermore, surgical treatment may lead to severe and resistant chronic low back pain, which may be worse than the initial condition (A.11).

2. *Natural history and relationship to impairment*

Low back pain is a very frequent condition, which has the reputation to resolve spontaneously in most cases. Nevertheless, a significant part of patients will suffer from prolonged pain, which may become chronically disabling (A.13).

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According to European guidelines (A.14):

- acute LBP is usually self-limiting (recovery rate 90% within 6 weeks),
- but 2%-7% of people suffering from acute LBP will develop chronic pain.
- Recurrent and chronic pain account for 75% to 85% of total workers' absenteeism.

The lifetime prevalence of low back pain is up to 84%. After an initial episode of LBP, 44 -78% people suffer from pain relapses and relapses of work absence are observed in 26-37% of cases (A.3).

American guidelines (A.15) are based on a similar statement:

- LBP occurs in about 80% of people [*evidence C**].
- Within 6 weeks, 90% of episodes will resolve satisfactorily regardless of treatment [*C**].
- Of all persons disabled for more than 1 year, 90% will never work again without intense intervention [*C**].

LBP is also the leading cause of disability in people under 45 years of age and the third cause of disability in those over 45 years of age. (A.13). Lifetime return to work rates decrease to:

- 50% if the injured worker is off work for 6 months,
- 25% if off work lasts 1 year,
- and nearly 0% if the worker has not returned to work within 2 years (A.13).

3. Medical diagnosis

Most patients arrive in our department with a diagnosis of lumbosacral radiculopathy caused by herniated lumbar disc.

This initial diagnosis has been previously established by the referring specialist according to the National regulations. However, the PRM specialist may call for an interdisciplinary meeting in order to revise this diagnosis if any doubt is raised after the admission evaluation of the patient.

In our department, within the frames of the programme, we deal with LBP & radicular pain **at any phase of its development**. Each stage is defined according to the European Guidelines (A.14):

- acute LBP = an episode of LBP persisting for less than 6 weeks;
- sub-acute LBP = LBP persisting between 6 and 12 weeks;
- chronic LBP = LBP persisting for 12 weeks or more.

B. ACTIVITY LIMITATIONS

LBP with lumbosacral radiculopathy can limit daily activities requiring the use trunk and/or lower limbs, such as changing and maintaining body position, walking, going upstairs, carrying and handling objects (e.g. holding a grocery bag), dressing the lower body, washing oneself, toileting (the last three mentioned are mostly related to the acute phase) (A.16, A.17).

Furthermore, patients suffering from pain develop fear of movement and (re)injury and they reduce their activity level. Progressive decrease in functional abilities leads to the low levels of aerobic fitness and the intolerance to physical activities: this is the **deconditioning syndrome** which is the main target of functional training programmes.

C. PARTICIPATION RESTRICTIONS

LBP with lumbosacral radiculopathy may restrict the patient's participation in familial life (doing household tasks, caring for household objects and assisting others). Long work absenteeism can affect the patient's work and remunerative employment perspectives. LBP and radicular pain also limits the patient's participation in leisure and sports activities (A.16, A.17).

D. SOCIAL AND ECONOMIC CONSEQUENCES

1. *Epidemiological data*

At the National level, epidemiological data on LBP with lumbosacral radiculopathy are not available. But an epidemiological study has been performed in our Department, in order to analyse the scope of out-patient comprehensive rehabilitation performed in the Centre of the Rehabilitation, Physical and Sport Medicine (B.2).

The retrospective data of 233 patients cared in 2006 and 2007 revealed that **155 of them suffered from back pain with related neurological involvement (67%)**.

Sex: 34% of the 155 LBP patients were males and 66% were females.

Age: it ranged from 24 to 81 years (mean mean 51 years). The highest percentage of programme attendees was observed in age groups **40 - 49 years** and **50 - 59 years** (52% of patients for both groups). A total of 73% patients were in under 60 years. Since the retirement age in our country is: 62.5 years for males and 60 years for females, a large majority of these patients was then at working age. This is consistent with other data from the International literature, which show that LBP is most frequent in the working age population (A.18, A.19).

Educational level: this information was available for 129 (83%) patients: 59 of them had a university degree (38%) and 13 had a high school degree (89%) The rest of patients (37%) had a poor educational level.

Social status: on their arrival, 105 patients (68%) were working on a daily basis; 25 patients (16%) were retired; 18 patients (12%) already had a disability status, 7 patients (4.5%) had another social status (e.g. students, women on maternity leave, etc).

Pain location: 135 patients (87%) had low back pathology, 19 patients had cervical disorders (12%), and only 1 patient suffered from the thoracic spine (0.6%).

2. *Social and economic data*

The direct financial costs of back pain are health care costs, and indirect are related to working absenteeism, i.e. production losses and impact on insurance costs (A.18).

There is no national economic analysis available about Lithuania. According to the literature:

- in UK, LBP is one of the most expensive conditions for which an economic analysis has been carried out. In 1998, the direct healthcare costs for back pain in the United Kingdom were estimated at £1632m (\$2932m; €2423m), with physiotherapy accounting for £251m. (A.20).
- In Norway, the total cost has been estimated 13-15 billion NOK a year. About 50% of this amount is the cost of social benefit, while commerce accounts for 25-30%. In 1995 there were more than 35 000 people who were on disablement benefit due to back problems, and each year 3000-4000 are added due to the same cause (A.21).

Back problems are thus one of the most frequent single reasons for disablement benefit. Among people on sick leave or rehabilitation in 1995, 15-17 % named back problems as the cause of their situation. The same did 13 % of those on disablement benefit (A.21).

E. MAIN PRINCIPLES OF YOUR PROGRAMME

The organization of the Programme is based on:

- National Regulations,
- The White Book on Physical and Rehabilitation Medicine in Europe,
- International Scientific guidelines and recommendations.

1. *Legal framework of the programme*

The programme is managed according to strict regulations issued by the Lithuanian Ministry of Health:

- Inclusion/exclusion criteria and time frames are clearly defined: “every patient of any gender aged 18 and over, suffering from low back pain with corresponding lumbosacral radiculopathy, causing person’s moving or self-care impairment is entitled to the course of comprehensive out-patient rehabilitation, lasting 14 consecutive working days”.
- Patients inclusion is based on a medical diagnosis established before the admission by a referring specialist, i.e. neurologist, neurosurgeon, orthopaedist.
- Acute radicular pain is treated apart in a relevant “acute care department” before the admission in the PRM programme, since outpatient PRM departments are considered as third care facilities.

Duration of stay in this programme is strictly limited to 14 days, which may be insufficient to achieve full recovery, but helps to settle the milestones of a self-rehabilitation programme.

2. *International Scientific guidelines and recommendations*

The main references used in this Programme are:

- European Guidelines for the management of acute non-specific low back pain in primary care (A.14),
- European Guidelines for the management of chronic non-specific low back pain (A.3),
- European Guidelines for prevention in low back pain (A.22),
- Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society (A.23).

3. *Main features of the Programme*

In accordance with Lithuanian regulations, patients with predominant acute radicular pain are treated in relevant acute care departments. They are admitted at a stage when radicular pain has become milder, so that the main target of our PRM programme is the treatment of low back pain.

The basic goals of the Programme are to relieve pain, to improve patient’s functioning and activity, to enable participation, to reduce sick-leaves duration and working absenteeism, to prevent pain recurrence and chronicity. Daily living is a keystone of quality of life. Therefore, resuming daily living activities is an important goal of our programme, besides the return to work. We consider that return to work as a sole outcome is not sufficient because:

- this would exclude many patients who did not work before the episode of LBP with lumbosacral radiculopathy (housewives, elderly people),
- return-to-work strongly depends on external factors (e.g. economic situation in the given region or profession), and
- return-to-work and function are strongly correlated, but do not represent the same underlying construct. (A.24)

1 **Our management of LBP refers to international guidelines (A.3, A.14, A.22, A.23, A.25)**
2 although scientific evidence is still lacking for some physical techniques. As it is stated in
3 European guidelines: “It is possible that many of the treatments that ‘we cannot recommend’ in
4 these guidelines (owing to lack of/conflicting evidence of effectiveness) may indeed prove to be
5 effective, when investigated in high quality randomized controlled trials” (A.3).

6 **Our programme is based on an individual approach of each patient** and takes in account
7 the pain stage. During the **acute phase** we put emphasis on pain relief (using massage, spinal
8 manipulations, tractions, physical techniques), patient education and conservative home self-
9 care. During the **sub-acute or chronic phase**, more importance is given to exercise therapy,
10 psychological assessment and management, recruiting psychotherapeutic techniques,
11 relaxation training and patient education

12 The programme takes into account the biopsychosocial model of LBP and is performed by a
13 multidisciplinary team under the PRM specialist’s supervision.

IV. Aims and goals of the Programme

A. TARGET POPULATION

1. Inclusion/exclusion criteria

The inclusion and exclusion criteria to the programme are defined in the National Ministry of Health Order No V - 50, 2008 (B.1):

Indication for comprehensive out-patient rehabilitation is lumbosacral radiculopathy causing person's moving or self-care impairment. The causes of lumbosacral radiculopathy are: herniated lumbar disc, spondylosis, spinal stenosis, which clinical presentation may come in different variations: lumbosacral radiculopathy alone, combined with LBP or LBP combined with corresponding radiculopathy.

The pain intensity on arrival is moderate: VAS of low back pain is 46mm, average VAS of leg pain is 38mm. Therefore, the patient condition is compatible with a rehabilitation programme. Patient. Severe radicular pain is treated in acute care settings, which we cooperate with.

Exclusion criteria are defined by an official list of general contraindication for rehabilitation.

In practice, patients are excluded only for very serious, sometimes life threatening conditions, requiring appropriate treatment in specific care, so that patient is such conditions can't actively participate in a comprehensive

The official list of general contraindications for rehabilitation

- uncorrected metabolic diseases (diabetes mellitus, myxoedema, thyrotoxicosis);
- III° hepatic or pancreatic insufficiency;
- heavy or repeated haemorrhages of any reason or anaemia Hb<80g/l;
- parasitoses;
- acute infectious disease;
- active stage of any form of tuberculosis;
- patients with transmissible sexual diseases;
- mental illness with personality desocialisation;
- complicate ventricular rhythm disturbances,

rehabilitation programme. This is just a legal way to avoid misunderstanding between patients, their relatives and the referring physician. Mild comorbidities are not obstacles for rehabilitation.

If a patient's clinical situation corresponds to the mentioned contraindications, he/she has to be cared in a specific therapeutic unit or palliative setting. **When the clinical situation is stabilised and improved, the patient can then be referred to the rehabilitation unit.**

2. Referral of patients

Direct access to the PRM programme	Yes
Referral from general practitioners	Yes
Referral from other specialists	Yes
Referral from specialists in PRM	Yes

Most patients are referred to the Department directly by their general practitioner or by other consultants, e.g. neurologist, orthopaedist, PRM physicians. Since the Programme is held in a University Hospital, the patients are sent from different medical institutions, either national or

1 private: GP centres, out-patient clinics, district hospitals, etc. Sometimes, direct access of
2 patients without referral is possible as well.

3 **3. Stage of recovery**

4 Within two weeks of onset	Yes
2 weeks to 3 months after onset	Yes
3 months or longer after onset	Yes

5
6 Patients can be admitted at **any phase** of LBP with corresponding radiculopathy: acute,
7 subacute or chronic.

8 **B. GOALS OF THE PROGRAMME**

9 **1. In terms of body structure and function**

10

ICF code	ICF label
s760	Structure of trunk
b280	Sensation of pain
b710	Mobility of joint functions
b730	Muscle power function
b780	Sensations related to muscles and movement functions
b265	Touch function
b152	Emotional functions
b134	Sleep functions

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12 **2. In terms of activity**

13

ICF code	ICF label
d410	Changing basic body position
d415	Maintaining a body position
d430	Lifting and carrying objects
d450	Walking
d475	Driving
d510	Washing oneself
d540	Dressing

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1 **3. In terms of participation**

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ICF code	ICF label
d640	Doing housework
d650	Caring for household objects
d660	Assisting others
d850	Remunerative employment
d920	Recreation and leisure

3

4 The main goals of our Programme are expressed in the ICF categories included in the current
5 version of Comprehensive ICF Core Set for low back pain (**A.26, A.27**).

6 In our Programme, we have decided to emphasise some ICF categories which are not
7 included in the Brief Core Set for LBP. Those are: d475, d510, d650, d660, d920. The inclusion
8 of these categories was based on the RCT performed in the UK, which defined the importance
9 of mentioned categories, especially d650 ad d920, for patients with low back pain (**A.28**).

10 Therefore, our Programme does not focus on returning to job only, but also on other
11 participation aspects, because the attendees of our Programme are people with different social
12 backgrounds: working people, housewives, retired people, students and others.

V. Environment of the programme

A. CLINICAL SETTING

Individual practice or part of a doctor's group practice	No
Individual practice in a private hospital	No
Part of a local (public) hospital	No
Part of a regional hospital (or rehabilitation centre)	No
Part of a university or national hospital	Yes

The Programme is performed in an **out-patient rehabilitation department**, which is part of the Centre of Rehabilitation, Physical and Sport Medicine, in the University Hospital.

B. CLINICAL PROGRAMME

Inpatients in beds under PRM responsibility	No
Inpatient beds belonging to other departments	No
Day programme (most of the day in outpatient setting, not home)	Yes
Outpatient clinic (assessment and/or treatment, for up to 3 hours/day)	Yes
Community based (in the patient's home or workplace or other relevant community location, eg sports centre)	No

C. CLINICAL APPROACH

Uniprofessional	No
Multiprofessional	Yes

The main members of the multi-professional team are: a PRM physician, a physiotherapist, an occupational therapist, a psychologist, a social worker, a nurse.

It is possible to **cooperate on demand with other specialists**, e.g. neurologist, neurosurgeon, orthopaedist, psychiatrist, radiologist, dietician, orthotist and others.

D. FACILITIES

Does your programme have a designated space for:	
For assessments and consultations?	Yes
For an ambulatory or day care programme?	Yes
For inpatient beds?	No
For therapeutic exercises?	Yes
For therapeutic exercises?	Yes
For training in independence and daily living?	Yes
For vocational and/or recreational activities?	No

The Department is equipped with wide range of facilities that includes:

- 3 consultation rooms,
- 4 exercise rooms, one of them is equipped with a spinal traction system;
- 2 pools, one of them is equipped with a spinal traction device;
- 4 rooms of physical modalities: electricity (TENS), heat (shortwave and microwave diathermy), cryotherapy, laser therapy, ultrasound, magnetic field and hydrotherapy;
- 3 massage rooms;
- 1 room for training in independence and daily living;
- the room for acupuncture procedures and manual therapy procedures;
- some space designed for patients' rest.

VI. Safety and patient rights

A. SAFETY

The safety concerns of persons in the unit where the programme takes place, relate to :	
Emergencies (fire, assault, escape)	Yes
Medical emergencies	Yes
Equipment	Yes
Handling of materials	Yes
Transports	Yes
The safety of persons in the programmes of your unit is provided by :	
Written standards from National Safety Bodies	Yes
Written standards from National Medical Bodies	Yes
Unit-specific written rules	Yes
Periodic inspection	
Internal	Yes
External	Yes

The Department is equipped with a medical emergency kit. Since the Department is the part of a University Hospital, direct access to the emergency and critical care units is possible on demand.

The Department is equipped with fire extinguishers. The escape plan, in several copies, is displayed on the walls of the Department. A regular training is organized every year to teach the action plan in case of emergency, as well as the emergency exits.

Patients' safety within the Department is controlled by hospital management orders and by written standards from National Medical Bodies and National Safety Bodies.

Periodic internal and external inspections of the Department equipment, facilities and documentation are regularly performed.

B. PATIENT RIGHTS

Has your programme adopted a formal policy or statement of patients' rights?	Yes
Does this statement specify the influence that the patient should have in the formulation and implementation of the programme?	Yes
Is the statement known to all personnel involved in delivering the programme?	Yes
Is this checked periodically?	Yes

Is the statement made known to and is available to all persons visiting your unit?	Yes
--	-----

1 **Patient rights are based on the following International references, national law and**
 2 **internal rules:**

- 3 • WHO Declaration on the Promotion of Patient's Rights in Europe 1994, United Nations
 4 Charter, through its 1993 standards, the European Year for People with Disabilities,
 5 2003,
- 6 • the 58th Resolution of the World Health Assembly 2005 and its Disability and
 7 Rehabilitation Action Plan for 2006-2011,
- 8 • The United Nations Convention on the Rights of Persons with Disabilities, adopted on
 9 December 13 2006,
- 10 • National law on patient's rights 1996, newly edited 2004 (B.3) and
- 11 • the Department written specific safety rules, the last ones are displayed in the
 12 Department reception.

13 **The Programme is organized on the basis of the National Ministry of Health Order No V -**
 14 **50, 2008.** Any patient is informed of the Programme content on his/her arrival. Each patient
 15 signs an informed consent. The patient and his/her relatives are invited to participate in team
 16 meetings.

17 C. ADVOCACY

18 Give at least one example of how your organisation advocates for people your
 programme deals with:

Conferences

Yes

Brochure

Yes

19
 20 Our centre organizes conferences, where other medical specialists are also invited, in order to
 21 share information on rehabilitation issues and promote good health behaviour.

22 Our centre has published the self-care brochure on health back behaviour, which is given free
 23 of charge to every patient attending our Programme.

VII. PRM Specialists and team management

A. PRM SPECIALISTS IN THE PROGRAMME

Does your PRM physician have overall responsibility and direction of the multiprofessional team ?	Yes
Does your PRM physician have overall responsibility and direction of the rehabilitation programme, not only medical responsibility ?	Yes
Does he/she have a European Board Certification in PRM ?	Yes
Does he/she meet National or European CME/CPD Requirements ?	Yes
Number of CME or EACCME points earned in the last 3 years :	CME 24 pts ECTS 4 crds
The <i>two primary functions</i> for the PRM specialist in your Programme are to :	
Treat comorbidity	No
Assess the rehabilitation potential of the patient	Yes
Analyse & treat impairments	No
Coordinate interprofessional teams	Yes

The PRM specialist has an overall leadership on the team and is “the patient’s manager”.

He/she is responsible for the initial patient’s evaluation (clinical and functional), the set up of an appropriate PRM strategy and its implementation by the rehabilitation team. Team coordination is ensured by regular weekly team meetings.

According to the National regulation of State Health Care Accreditation Agency under the Ministry of Health, every medical specialist has to collect 120 hours of CME/CPD every 5 years in order to keep his/her valid practising specialist’s licence. At the moment, the submitter has 83 hours of national CME/CPD, earned during the last 2 years. Furthermore, the submitter gives lectures for medical professionals, taking place in the University Hospital.

Number of CME points, shown in the table above, have been earned by the submitter since 2008. On the basis of this programme, the submitter is preparing a Ph.D. work.

B. TEAM MANAGEMENT

Which rehabilitation professionals work on a regular basis (minimum of once every week) in your programme? (give the number)	
Physiotherapists	4
Occupational therapists	1
Psychologists	1
Speech & Language therapists	-
Social workers	1
Vocational specialists	-
Nurses (physical modalities applying)	4
Orthotists/prosthetists assistive technicians/engineers	On demand
Other (please specify): Massage specialists	3
How often does your staff receive formal continuing education	
In team rehabilitation :	Every year
In their own profession :	Every year
Do team activities in your rehabilitation programme include the following ?	
Is the patient at the centre of a multiprofessional approach?	Yes
Do you always give informed choices of treatment?	Yes
Do you regularly promote family involvement?	Yes
Does your organisation of multi professional team working include :	
Holding regular team meetings with patient's records only (more than 2 members)	Yes
Holding regular team meetings (more than 2 members) with the presence of the patients	No
Joint assessment of the patient or joint intervention	Yes
Regular exchanges of information between team members	Yes

The Programme approach is multi-professional. The main members of the multi-professional team are: a PRM physician, a physiotherapist, an occupational therapist, a psychologist, a social worker, a physical modalities applying nurse; upon the necessity there is the possibility to contact and collaborate with other specialists. Each member of the team evaluates the patient in the field of his/her competence.

The first team meeting is usually held within the first three days from arrival. During this meeting, the initial PRM strategy is adjusted and the rehabilitation plan is confirmed. Later on, rehabilitation process is regularly reviewed by the PRM specialist. The team work is supervised and coordinated during weekly meetings. In some cases team meetings include patients and their relatives, but this is not on regular basis.

As mentioned above, **every medical specialist has the legal obligation to collect a definite amount of CME/CPD hours**, in order to keep valid his/her practising specialist's licence. Therefore, every medical professional attends CME/CPD courses organised by high education institutions and participates in scientific events. This is completed by personal participation in scientific works, i.e. to give lectures, to publish articles in national journals.

VIII. Description of the programme

A. TIMEFRAME OF THE PROGRAMME

The time frame of the programme is clearly **defined by the National Ministry of Health Order**. Every patient suffering from LBP with lumbosacral radiculopathy is entitled to **14 working days spent in therapy facilities (B.1)**.

In practice, this time frame may differ with respect to individual situations (see chapter VIII D).

B. ASSESSMENT

1. *Diagnosis approach*

The patient's medical diagnosis is already available on arrival from his file (see IV.A. Target population).

The patients arriving for the course of comprehensive out-patient rehabilitation are fully examined before the Programme session (i.e. clinical evaluation and diagnostic imaging procedures: CT, MRI) and the clinical diagnosis is previously established in the referring institution by the managing specialist, e.g. neurologist, neurosurgeon, general practitioner. Then, the PRM physician of the referring institution performs a clinical assessment, evaluates patient's activity and performance and, according to the findings, refers the patient to our programme. On the base of these recommendations, the managing specialist signs up the referral to our institution for the programme attendance. Such consultations are mandatory in order to get a course of comprehensive rehabilitation paid by the State Patient Fund.

In our Department, PRM physician performs the patient's assessment on admission to the Programme. If his own examination raises some doubts about the established clinical diagnosis, the PRM specialist has the right to organise a joint consultation with 2-3 PRM physicians, one of them being the Head of the Department, in **order to clarify the diagnosis**. If our registered clinical findings **significantly differ** from those described by the referring doctor, or if we have suspicion of serious spinal pathology, then we perform blood, urine tests, lumbar spine X-ray and if the abnormalities are observed, we refer the patient to his/her GP, who is responsible for further patient's management.

Within the course of the Programme, usually, we do not repeat diagnostic tests, especially if there are **no significant differences or symptoms worsening** in the clinical examination, since patients attending our Programme are **fully examined beforehand** by the referring doctor.

2. *Impairment*

a) **Clinical assessment**

- Detailed patient's history taking, in order to exclude possible "red flags".
- Pain rating, using Visual Analogue Scale (VAS), Numerical Rating Scale (NRS).
- Physical evaluation:
 - inspection of posture, spinal deformities;
 - palpation for muscles, facet joints and spinal processes tenderness;
 - range of motion (ROM) – flexion, extension, lateral bending using finger-to-toe test, modified Schober test, inclinometer;

- 1 ○ neurological evaluation, in order to detect an existing neurological deficit, that
- 2 ○ may impact patient's functional performance:
- 3 ○ straight leg raising test;
- 4 ○ manual muscle testing using Lovett scale,
- 5 ○ sensory testing with pinprick sensation especially in the medial, dorsal and
- 6 ○ lateral aspects of the foot;
- 7 ○ tendon reflex testing;
- 8 • Psycho-emotional evaluation using Hospital Anxiety and Depression Scale (HADS),
- 9 Zung Self-Rating Depression Scale - performed by psychologist, to evaluate the
- 10 possible predictors of chronicity.

11 **b) Diagnostic tools (instrumental functional assessment)**

12 Besides the clinical assessment, patients, undergoing the Programme, are **additionally**

13 instrumentally assessed using the new device - *the Insight Subluxation Station™*. (A.29, A.30).

14 This is a 5-technology unit, measuring:

- 15 • Infrared thermography of the trunk, using Rolling Thermal Scanner;
- 16 • Spinal Range of Motion, using wireless Inclinometer;
- 17 • Patient self-reported pain threshold, using Algometer;
- 18 • Heart wave variability, using Pulse profiler;
- 19 • Surface EMG, using 2 channel Static and/or 4 channel Dynamic EMG sensors,

20 It provides a comprehensive picture of patient's neurospinal condition.

21 Although the scientific references from indexed medical journals and official websites

22 regarding this device's validity and reliability are still not available, we try it with the purpose to

23 perform the evaluation of its relevancy through the forthcoming studies.

24 **3. Activity and participation**

25 Low back pain with lumbosacral radiculopathy can restrict person's activity and functioning in

26 various life aspects with their negative consequences.

27 **Activities** of single functions performed by the patient and more complex activities **are usually**

28 **evaluated:**

- 29 • ability to change body position from lying to sitting,
- 30 • ability to change body position from sitting to standing,
- 31 • ability to maintain body position,
- 32 • ability to stand (bare weight) on one leg,
- 33 • ability to squad down,
- 34 • walking,
- 35 • climbing stairs(whether using alternating steps or not),
- 36 • ability to perform activities of daily living (washing oneself, dressing, toileting).

37 **Patient's performance** is mainly analysed through standardized questionnaires. We use the

38 **Oswestry Disability Index** and the **Roland-Morris Disability Questionnaire**. Both of them

39 are the commonly used outcome-measure questionnaires for low back pain. They are self-

40 administered disability measures, based on a patient's subjective impression of his or her own

41 state of disability.

42 The Oswestry Disability Index (**ODI**) is divided into ten sections, each followed by six

43 alternatives, designed to assess limitations of various activities of daily living. Each section is

44 scored on a 0–5 scale, 5 representing the greatest disability. The index is calculated by

45 dividing the summed score by the total possible score, which is then multiplied by 100 and

46 expressed as a percentage. The higher percentage score is, the more disabled the patient is.

47 The Roland Morris Disability Questionnaire (**RMDQ**) is a self-administered disability measure

48 consisting of 24 statements, covering a broad range of activities: mobility, self-care and

49 sleeping. 24 items of this questionnaire are scored at 0 or 1. General score available from 0 to

50 24 points, where higher scores representing greater levels of disability.

1 Differently from the **RMDQ**, the **ODI** provides as additional information about pain intensity,
2 patient's social life restrictions.

3 We also assess how LBP impacts the person's activity and participation according the ICF
4 codes and category titles, which are included in the **Comprehensive ICF Core Set for Low**
5 **Back Pain**.

6 **4. Environmental and personal factors**

7 Familial and social factors are evaluated through the interview of the patient: e.g. marital
8 status/distress, family status/distress, economic status, financial security, social withdrawal.

9 We also ask the patient about his working environment and try to assess his capability to
10 perform his professional activity.

11 Socio-economic parameters (e.g. days of sick leave) are used to evaluate social or
12 occupational participation problems. For the evaluation of personal factors and
13 psychological/behavioural assessment, we use standardised questionnaires (HADS, Zung
14 Depression Scale).

15 **5. Criteria for progress measurement**

16 Progress measurement is performed on the basis of patient's subjective feelings and team
17 members' observation.

18 The patient's progress is measured by clinical assessment and functional assessment,
19 evaluating standardised activities of single functions performed by the person and complex
20 activities, as described above in this Chapter.

21 Therefore, decrease of pain (VAS - Visual Analogue Scale), increase in range of spinal motion
22 (finger-to-toe test, modified Schober test of spinal mobility), increase of the angle of SLR test
23 (straight leg raising test), increase in affected leg muscle strength, improvement of mobility,
24 daily living activities and participation (Oswestry LBP Disability Questionnaire), improvement of
25 psycho-emotional status (HADS, Zung Depression Scale) are criteria for progress
26 measurement.

27 **C. INTERVENTION**

28 **1. PRM specialist intervention**

29 The PRM physician is responsible for the initial patient's evaluation, **appropriate PRM**
30 **strategy** set up, team coordination and further patient's follow-up.

31 The patient's follow up is scheduled on a planed protocol, usually every third working day/or
32 day spent in therapies, or more on demand.

33 The individual patient's PRM programme is adjusted on every visit, according to the
34 assessment findings. The PRM doctor can prescribe relevant **drugs** in addition to the
35 rehabilitation procedure.

36 **During the course** of the Programme, if a plateau in the patient's progression is caused by
37 persistent pain, the PRM physician refers the patient to the Pain Clinic Specialist in order to
38 discuss a spinal injection.

39 **In case of neurologic complication** (i.e. progressive or severe neuromotor deficit or
40 persistent neuromotor deficit after four to six weeks of conservative treatment, cauda equina
41 syndrome) the patient is referred to a spine surgeon in order to discuss a releasing surgery.

42 **2. Team intervention**

43 **a) General view**

1 The members of the team evaluate the patient subsequently. The first team meeting is usually
 2 held within first 3 days from the arrival, during this meeting the initial PRM strategy is adjusted
 3 according to the team members' evaluation results and rehabilitation plan is confirmed.

4 **According to National regulations**, during the course of comprehensive out-patient
 5 rehabilitation due to lumbosacral radiculopathy, every patient must get, **within 10 working**
 6 **days**, a minimum amount of the following procedures:

- 7 • physiotherapy (training exercises) – 10 sessions,
- 8 • occupational therapy - 4 sessions,
- 9 • psychotherapy - 2 sessions,
- 10 • physical modalities - 9 sessions,
- 11 • massage - 4 sessions,
- 12 • social worker consultation – 1 session,
- 13 • patient's education – on demand.

14 **In practice**, this has been actually implemented. Every patient is assigned to a individual
 15 rehabilitation programme based on the average intervention terms, as mentioned above. But,
 16 the amount of intervention can be modified with regard to the individual clinical and functional
 17 evolution. All changes are expressed in medical documents.

18 **According to his individual rehabilitation plan**, each patient attending the Programme gets
 19 from 3 to 5-6 different kind of interventions, such as:

- 20 • training exercises in room,
- 21 • training exercises in pool,
- 22 • physical modalities applying,
- 23 • patient education,
- 24 • psychotherapy,
- 25 • behavioural therapy,
- 26 • massage etc.

27 Thus, the patient spends up to 3-4 hours daily in the Programme.

28 **b) Detailed responsibilities of team members**

29 **The physiotherapist** evaluates and manages disorders of patient's motion using passive and
 30 active exercises. Exercise therapy has become a standard for the management of spinal care.
 31 However, there is conflicting evidence in favour of one exercise over the other – flexion,
 32 extension, fitness (A.11, A.12). The physiotherapist creates the initial exercise program based
 33 on the assessment of the patient and according to the phase of pain.

34 The main goal of exercise therapy in case of acute phase is to adapt exercise to pain in order
 35 to maintain a relevant level of activity. So the initial exercises, movement into flexion or
 36 extension are determined by the exercise-preferences of both the patient and physiotherapist,
 37 depending on which activity does not exacerbate pain. Patients are advised to stay active and
 38 continue ordinary activity within the limits permitted by the pain, but discontinue any activity or
 39 exercise that causes a spread of symptoms.

40 In case of sub-acute and chronic phase, we put emphasis on specific exercises to strengthen
 41 the core trunk stabilising muscles, to improve postural function and to improve patient's
 42 functioning.

43 Aerobic training is promoted in any phase in order to fight against deconditioning syndrome.

44 The patient is educated regarding the home exercise programme, is informed about its
 45 importance and encouraged to continue it on his own.

46 **The occupational therapist** assesses the activities of daily living and occupational activities. He/she
 47 trains the patient skills to overcome barriers to activity of daily living and he/she consults the patient on
 48 his/her work environment, ergonomics at work.

49 OT is one of the team members responsible for patient's education, especially during the acute phase of
 50 pain, which includes:

- 51 • limited bed rest,

- 1 • postural advice,
- 2 • encouraging remaining active and continuing ordinary daily activity within the limits permitted by
- 3 pain,
- 4 • avoiding specific activities known to increase mechanical stress on the spine,
- 5 especially prolonged unsupported sitting, heavy lifting, and bending or twisting the
- 6 back, especially while lifting,
- 7 • and finally early return to work or other activities.

8 **The psychologist** evaluates patient's psycho-emotional condition, using standardised
 9 questionnaires (HADS, Zung Depression Scale), assesses psychological risk factors, "yellow
 10 flags". He/she applies psychotherapeutic techniques and relaxation training according to the
 11 evaluation findings

12 **The nurse** performs physical modalities prescribed by the PRM specialist, such as TENS,
 13 heat, cryotherapy, laser therapy, ultrasound, magnetic field. In every single case the type of
 14 applied physical modality depends on individual clinical situation and existing co-morbidities.

15 **The massage specialist** performs procedures of classical professional massage, massaging
 16 the body area prescribed by the PRM physician.

17 **The social worker** cooperates with various governmental institutions on demand, e.g.
 18 Disability and Working Capacity Assessment Office at the MSSL (Ministry of social security
 19 and labour), municipal or district social care departments or non-governmental patients
 20 organizations.

21 **D. DISCHARGE PLANNING AND LONG TERM FOLLOW UP**

22 **The date of discharge is scheduled in advance**, with respect to National regulations (B.1).
 23 However, during the course of the Programme, the date of discharge can be adapted to the
 24 patient's progress, which is discussed with team members on weekly meetings.

- 25 • If the patient reaches the determined aims and his/her rehabilitation potential is fulfilled
 26 earlier, the date of discharge is put forward.
- 27 • If the progress is slower and if patient's rehabilitation goals are not reached within 14
 28 days, it is possible to send a written request to the State Patient Fund in order to
 29 prolong the duration of the Programme. The State Patient Fund usually replies to our
 30 request within 1-2 working days. The request is sent in advance, on the 11-12th days of
 31 the programme, so that here is no break in the programme course. However, this is
 32 not a common situation.

33 **A final team meeting is held 2-3 days before the predicted discharge day**, The team
 34 discusses on the patient's progress and the PRM specialist makes the general decision about
 35 the date of discharge or programme prolongation.

36 Patients who have completed our programme, are encouraged to continue a self rehabilitation
 37 programme on their own and, to attend the good health behaviour group held in our
 38 department's pool under the supervision of a physiotherapist. If during the final team meeting,
 39 it is decided that for any individual patient the self rehabilitation programme is not enough, we
 40 refer him/her to continue programme content in their municipal primary outpatient health care
 41 institution under the supervision of specialists. Besides, every patient who has completed the
 42 programme is advised to come to our department for the reassessment and outpatient
 43 consultation after 3-6 months. All the recommendations are written in a standardised discharge
 44 report for the patient and his/her GP.

45 **The long term outcomes monitoring of our patients has been started last year**, as a part
 46 of a Ph.D. project. Additionally to the Programme, patients are invited attend a follow up
 47 assessment in our Department, after 6 months, on voluntary basis. The data collection and
 48 analysis is in progress.

49

IX. Information management

A. PATIENT RECORDS

Do the rehabilitation records have a designated space within the medical files ?	Yes
Do you have written criteria for :	
Admission	Yes
Discharge	Yes
Do your rehabilitation plans include written information about aims and goals, time frames and identification of responsible team members ?	Yes
Do you produce a formal discharge report (summary) about each patient?	Yes

B. MANAGEMENT INFORMATION

Does your programme show evidence of sustainability?	
Established part of public service :	Yes
Has existed for more than 3 years :	Yes
Has received national accreditation (where available) :	Yes
How many new patients (registered for the first time) are treated in your programme each year :	130-166
In your day care or inpatient programme :	
What is the mean duration spent in therapy by patients on this programme	15.28 days
How many hours a day do the patients spend in therapy.	3-4 hours
Give the mean duration of stay spent in the programme :	21.09 days

The data in the above table describe the mean duration of stay in the Programme and the mean duration in days spent in therapy up to December 31st 2009, when the determined time frame of the Programme used to be **16 days spent in therapy**. This duration was reduced to **14 days spent in therapy**, on December the 3rd 2009 by the order Nr. V – 988, coming into force on January the 1st 2010.

The number of new patients treated in our programme is increasing. As it was mentioned in Chapter IV, during the period of 2006 – 2007, 135 had attended our Programme; the number of patients registered in our Programme in 2008 was 166 (this increase happened due to some changes in National regulations) and remains similar.

C. PROGRAMME MONITORING AND OUTCOMES

Does your programme have an overall monitoring system in addition to patient's records ?	Yes
Are the long term outcomes of patients who have completed your programme regularly monitored ?	
Impairment (medical) outcomes :	Yes
Activity/Participation (ICF) outcomes :	Yes
Duration of follow up of the outcomes :	3-6 months
Do you use your outcome data to bring about regular improvements in the quality of your programme's performance ?	Yes
Do you make the long term overall outcomes of your programme available to your patients or to the public?	No

All patient's medical and functional information, assessment and further monitoring data is recorded manually in standardised medical documentation. These documents are stores in the clinical archive, so they are accessible for periodic internal or external audit and outcomes assessment.

The long term outcomes monitoring of our patients was started last year and the analysis of data is in progress.

As a first overall outcome of our programme, we can mention that:

- on arrival, average VAS of low back pain is 46mm, average VAS of leg pain is 38mm;
- on discharge, 23mm and 20mm respectively.

X. Quality improvement

A. WHICH ARE THE MOST POSITIVE POINTS OF YOUR PROGRAMME?

The Programme is organized in a University Hospital, so all additional diagnostic, therapeutic and interventional means are available.

The Programme is funded by National Health Insurance (State Patient Fund) and is free for insured persons. Every insured person, suffering from low back pain with neurological involvement has the possibility to undergo the course of comprehensive out-patient rehabilitation according national legal regulations (B.1)

The Department has good means, in terms of equipment and competences for Programme implementation.

Comprehensive and individualised PRM programme is provided to every patient.

In the frames of the Programme, we mainly deal with working age people, whose main goals are to reduce pain and to return to job. So, implementation of our Programme helps to cut down the indirect costs, caused by this pathology.

Long term outcomes monitoring of patients who have completed the Programme is in progress.

The Programme can provide data for setting national guidelines of ICF implementation.

B. WHICH ARE THE WEAKEST POINTS OF YOUR PROGRAMME?

Programme advocacy is not sufficient.

The division of responsibilities and tasks between PRM specialists and other specialists may cause delays and management difficulties. This can alter the performance of our programme. PRM specialists should obtain the full responsibility of the patient during the course of the Programme, especially for the medical diagnosis revision.

Our staffs providing the Programme have no skills in interventional procedures (e.g., selective spinal injections).

C. WHICH ACTION PLAN DO YOU INTEND TO IMPLEMENT IN ORDER TO IMPROVE YOUR PROGRAMME?

1. *Intrinsic improvement*

To develop advocacy of the Programme in order to promote good health behaviour. This is going to be performed in a variety of formats, e.g. visiting working environment with lectures on healthy backs behaviour, visiting sport and leisure centres, possibly creating our website; in accessible and understandable terms, and in different languages, where appropriate.

To promote the scientific activities and research works in the field of low back pain rehabilitation. A Ph.D. project on the basis of the Programme and data analysis is in progress.

To publicise the benefits of low back pain rehabilitation.

To induce the development of National health care standards for people with low back pain.

To induce the development of National guidelines for implementation of ICF for low back pain.

1 **2. *Extrinsic demands***

2 To improve the cooperation with other teams and consultant-specialists.

3 To learn the practice of spinal injections techniques.

4

5

1

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37

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