Opinion of the Czech Society of Nuclear Medicine of the Czech Medical Association of J. E. Purkyně on the ^{177}Lu-PSMA therapy for prostate cancer

The basic prerequisite for successfully putting ^{177}Lu-PSMA therapies into practice in the field of nuclear medicine under the conditions of the Czech Republic is the emphasis on strict individualisation. Individualisation includes an assessment of the patient's health status, his/her ability to follow instructions relevant to radiation protection, the need for hospitalisation with regard to the exposure of people living in the same household and radioactive waste management, but also an assessment of the need and extent of dosimetry.

Outpatient administration of ^{177}Lu-PSMA therapy is possible only if the performing nuclear medicine centre ensures:

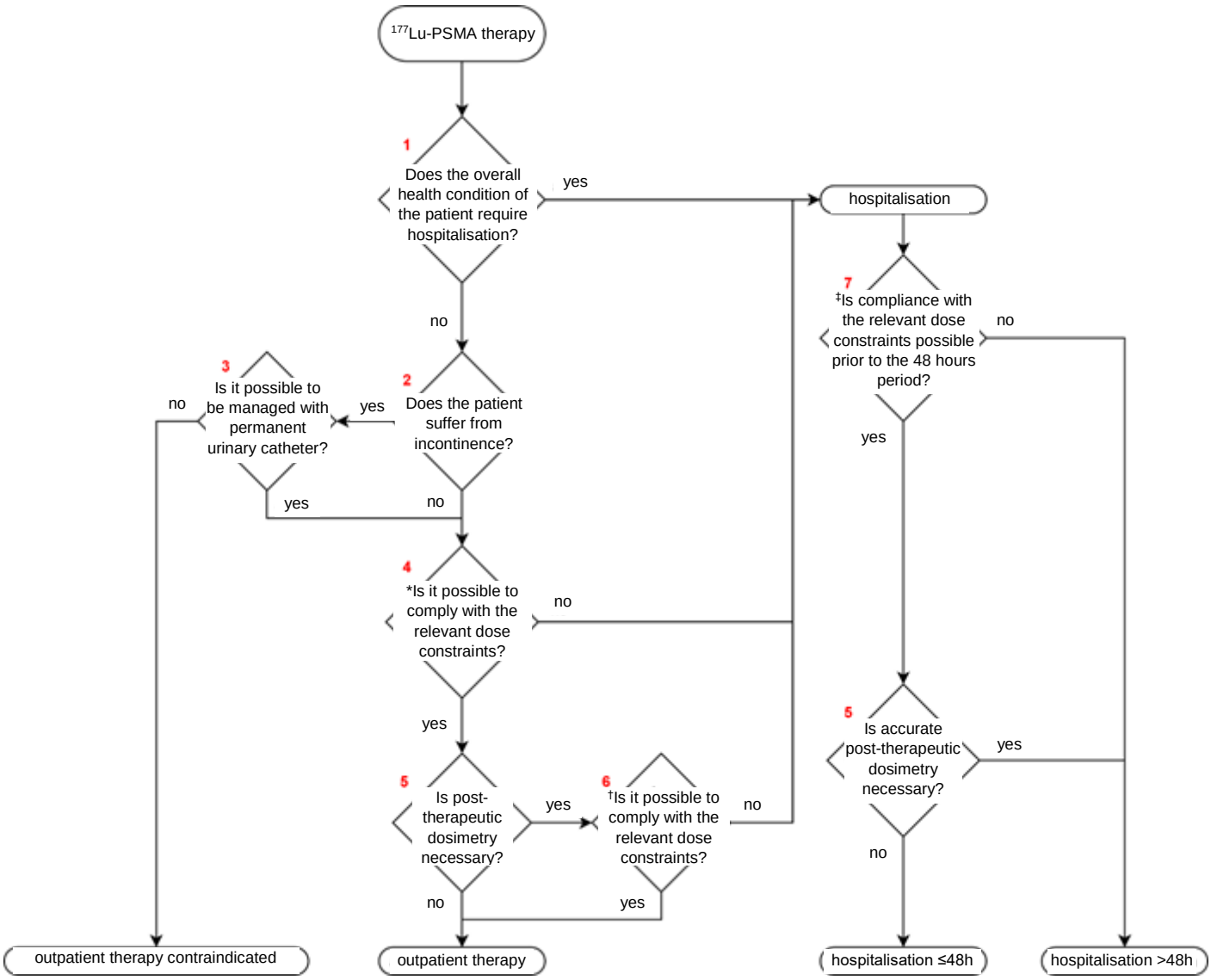
- patient education regarding radiation protection and waste management after leaving the centre
- continuity of health care for patients whose health condition suddenly deteriorates for any reason while staying in the centre
- sufficient information about procedures for complications in the home environment
- drawing-up of written procedures for this case or for the case of death of the patient at home, as part of the documentation for ^{177}Lu-PSMA therapy.

Possibilities of reducing the exposure of these people and to individualise patient education depending on the age of the people living in the household must be considered when assessing the possibility of compliance with dose constraints (DOM) for people living in the same household.

In the case of proof of compliance and optimisation of dose constraints for the population, a single exposure of the population is always taken as a model example. Repeated exposure of the same random persons during subsequent therapies is considered unlikely.

Any medical indisposition of the patient under the outpatient scheme for the administration after leaving the centre shall be treated as a single exposure of the assisting persons. The population exposure limit (1 mSv/year of effective dose) would be exceeded after more than 10 hours of close contact with the patient shortly after the administration of the therapy.

Patients under the outpatient scheme and after leaving the hospital will be provided, without exception, with a bracelet with information about the administration of ^{177}Lu-PSMA, a QR code referring to the brief instructions of the parties providing protection to the emergency personnel, and contact information of the centre that performed the administration, which can be contacted for advice, if necessary.
A patient with an increased risk of sudden medical indisposition cannot be automatically included in the outpatient scheme; this risk must be assessed by the indicating physician (possibly in collaboration with the competent specialist) and only then decide on outpatient or inpatient administration.


177Lu-PSMA therapy
1
Does the overall health condition of the patient require hospitalisation?
yes
hospitalisation
no
2
Does the patient suffer from incontinence?
3
Is it possible to be managed with permanent urinary catheter?
yes
no
yes
no
4
*Is it possible to comply with the relevant dose constraints?
no
yes
5
Is post-therapeutic dosimetry necessary?
yes
6
†Is it possible to comply with the relevant dose constraints?
no
no
yes
7
‡Is compliance with the relevant dose constraints possible prior to the 48 hours period?
no
yes
5
Is accurate post-therapeutic dosimetry necessary?
yes
no
outpatient therapy contraindicated
outpatient therapy
hospitalisation ≤48h
hospitalisation >48h

[Decision-making criteria] for the course of therapy and consequences of decisions:

[1] Does the overall health condition of the patient require hospitalisation?

- If the patient's health condition requires hospitalisation, the centre shall decide to perform the therapy in this way. Conditions requiring hospitalisation include any concurrent disease that would represent an increased risk of complications in the early period after the administration of ^{177}Lu-PSMA, both health complications and those related to compliance with radiation protection.

[2] Does the patient suffer from incontinence?

- If the patient suffers from urinary incontinence, which is not solved by permanent urinary diversion, or **[3]** is possible to be managed with permanent urinary catheter for as long as necessary, therapy cannot be performed.

[4] *Is it possible to comply with the relevant dose constraint?

- The patient's home environment and the agreed scheme-related measures allow compliance with dose constraints for persons living in the same household as well as the population. The following are considered scheme-related measures:
  - A structured educational interview will take place with the patient prior to the administration of ^{177}Lu-PSMA, according to the attached report, in the presence of a nuclear medicine physician and a medical physicist, where appropriate. The principles of conduct after the administration of the radiopharmaceutical are explained to the patient and the patient has the opportunity to ask supplementary questions. With his/her signature, he/she indicates that he/she has understood the information provided and that he/she undertakes to comply with the instructions relevant to compliance with radiation protection.
  - The patient shall leave the nuclear medicine centre at least 6 hours after the administration. Before leaving, the dose rate shall be measured at a distance of 1 m from the body and recorded in the medical records.
  - Transportation from the centre must be individual and arranged for by a person who provides assistance to a natural person undergoing medical exposure. For 48 hours after the administration, it is strongly recommended not to travel by means of public transport and the patient must confirm in writing that he/she will comply with this education.
  - For 24 hours after the administration, the patient shall observe self-isolation inside the home.
  - For 7 days after the administration, the patient shall use only his/her own hygiene products, dishes and clothes. The patient shall always urinate while sitting down, flush twice. All patient clothes and used textile hygiene products must be washed twice after use. Used dishes shall be washed thoroughly under running water in the case of manual washing. If a dish towel is used, only for a dedicated set of dishes. In the case of using a dishwasher, the longest possible program shall be chosen; separate washing and a separate set of dishes is not necessary.
  - If the patient is a working person without subsequent incapacity for work and the nature of his/her work makes it possible to ensure that the dose constraints for the population are not exceeded, he/she can return to work after 72 hours. In more complicated cases (long-term stay in the vicinity of co-workers, work with persons under the age of 18 years, etc.), it is necessary to proceed on an individual basis.
  - Inability or unwillingness to follow radiation protection instructions, or any identified infringement thereof are the reason for not starting/terminating the ^{177}Lu-PSMA therapy.

[5] Where standard distribution of the radiopharmaceutical in the patient's body is expected, dosimetry of target tissues is not currently performed and post-therapeutic dosimetry is not considered necessary. However, dosimetry should be performed if there is a risk of deviations to occur in the biokinetics of the radiopharmaceutical for the patient. This includes but is not limited to suspected kidney disease, in which a significant prolongation of the effective half-life of the radiopharmaceutical can be expected. Accurate dosimetry is then recommended for the 1st therapeutic cycle.

[6] †If it is possible to ensure **[4]** for the patient, post-therapeutic dosimetry can be performed on an outpatient basis. Taking into account the dose constraints of people living in the same household and the population and the required accuracy of dosimetry, the time interval between measurements and their number shall be chosen.

[7] ‡If, on the basis of the previous decision-making criteria, the patient is hospitalised and it is not possible to comply with the dose constraints for persons in the same household and the population within 48 hours after the hospitalisation, hospitalisation for more than 48 hours shall be taken. If hospitalisation is chosen within 48 hours, measures from **[4]** valid for more than 48 hours must be followed.

References:

[Herrmann] Ken Herrmann, Kambiz Rahbar, Matthias Eiber, Bernd J. Krause, Michael Lassmann, Walter Jentzen, Lars Blumenstein, Patrick Klein, Jean-René Basque, Jens Kurth, Dosimetry of 177Lu-PSMA-617 for the treatment of metastatic castration-resistant prostate cancer: results from the VISION trial sub-study. DOI: 10.1200/JCO.2022.40.6_suppl.097 Journal of Clinical Oncology 40, no. 6_suppl (February 20, 2022) 97-97.