

Dossier System for Developing Reimbursement Lists

Maria V. Sura
RC CEE&Ph, Russian National Research
Medical University, Moscow

The general situation in the Drug Lists formation in Russia

- Different levels
- Different rules and criteria
- Different commissions of experts
- Different budgets (federal, regional)

On-line system of Reimbursement Lists formation «Dossier» www.docie.ru



Автоматизированная система по формированию ограничительных перечней «ДОСЬЕ»



Московская область



Самарская область



Республика Татарстан



Сахалинская область

© 2012 г. Все права защищены. Интернет и дистрибуция ТМТ

Dossier system includes:

- Dossier form – application form for inclusion of drugs into Reimbursement List (30 sections)
- On-line database of reimbursed drugs and new drugs, proposed for inclusion, under different levels of expertise
- Analytical part

The main principles of Dossier System

- Evidence based medicine
- Economic evaluation
- Multilevel expertise
- Segmentation of patients
- On-line system
- Regional issues (morbidity, budget, practical experience etc.)
- Interregional cooperation
- Transparency of decision making



Dossier Form (1)

1. INN
2. Trade name
3. Original/Generic
4. Included in Reimbursement List or not
5. Manufacturer
6. Applicant
7. Pharmacotherapeutic group
8. ATC code
9. Are the diseases or social groups covered by the government resolution regulating access to Reimbursement on the regional level ?
10. Indications for Reimbursement List inclusion
11. Dosage
12. Dosage Forms
13. Course of treatment/lifelong prescription



Dossier Form (2)

14. Advantages of a new drug
15. Clinical effectiveness and safety (clinical trials)
- 15A. Level of evidence
16. Pharmacoeconomics
17. Clinical trials at the regional level or experience of application
18. Priority patient's groups (age, severity and duration of disease, complications)
19. Different indications (not for Reimbursement List)
20. Cost of one year treatment
21. The number of regional patients
22. Share and number of patients for prescribing of a new drug
23. Share and number of priority patients' groups for a new drug
24. Existing practice of patients' treatment
25. Presence of drug in different Drug Lists, Medical Standards, Clinical Recommendations
.....
26. Cost of illness
27. Exclusion of other drugs
28. Cost for inclusion of a drug into Reimbursement List for priority patients' groups
29. Training of physicians
30. References



Evidence based medicine: • meta- analysis • RCT	Economic evaluation: • Pharmacoeconomics research • Cost of one year treatment • Cost of illness • Cost for inclusion of a drug into Reimbursement List for priority patients' groups	Multilevel expertise: • Technical • Scientific • Formulary committee discussion
"Segmentation" of patients • Priority patients' groups (age, severity and duration of disease, complications) • Share and number of patients for prescribing of a new drug • Share and number of priority patients' groups for a new drug	Dossier System	Regional issues • Morbidity • Clinical trials at the regional level or experience of application • Existing practice of patients' treatment
On-line system www.docie.ru	Transparency of decision making: • approximately 25 experts • possibility to check each	Interregional cooperation: Cooperation at the level of experts and applicants

Advantages of Dossier System

- Systematization of information about reimbursed drugs;
- Common approach to filling the application form (Dossier) and conducting expertise of drugs;
- Multi-criteria analysis of drug data (effectiveness, safety, economic advantages, cost of illness, budget impact, existing practice of patients' treatment etc.);
- Possibility to plan the budget;
- On-line documents circulation;
- Analytical data processing



Questions for experts

- Is the drug effective?
- Is the drug safe?
- Is the drug efficient, cost-effective?
- What are the advantages (effectiveness, safety, cost....) of a new drug compared with reimbursed drugs?
- Does the drug have any economic advantages?
- What is the cost for inclusion of a drug into Reimbursement List (cost saving or extra costs)?
- How much money does the illness cost?
- Is the new drug included in any other Drug Lists, medical standards, clinical guidelines?



**Thank you very much for your
attention**

RC CEE&Ph, Russian National Research
Medical University, Moscow

Tel/fax: +7(499) 245 38 07

www.hta-rus.ru

