How to improve access to therapy?

A round the World Table: GERMANY

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HCV drugs available in Germany

- 2001 PEG-IFN a2a / RBV
- 2002 PEG-IFN a2b / RBV
- 05/2011 Boceprevir/P/R
- 07/2011 Telaprevir/P/R
- 01/2014 Sofosbuvir: SOF/P/R or SOF/R
- 05/2014 Simeprevir: SMV/P/R or SMV/SOF
- 08/2014 Daclatasvir: DCV/SOF
- 11/2014 Sofosbuvir/Ledipasvir (FDC)
- 1/2015 Paritaprevir/r/Ombitasvir/Dasabuvir (3D)
Germany: Access to Treatment

1. EMA approval

2. Reimbursement by health insurance
Germany: Access to Treatment

- Pricing according to the AMNOG law

- 1 year drug price according to pharmaceutical industry

- After first year pricing as a results of
  - GB-A judgement whether new therapy has additional benefit (Zusatznutzen) over standard of care (SOC) based on IQWiG (Institut für Qualitätssicherung und Wirtschaftlichkeit im Gesundheitswesen) evaluation
  - Final pricing following negotiations with the pharmaceutical industry based on GB-A judgement
Situation of Hepatitis C in Germany:

Present Discussion

- Is HCV therapy too costly?
- Extra HCV Budget „Sonderausgabenvolumen” for 2015 and 2016 approx. 1.4 Billion €
- Special contracts with Health Insurance Companies
Need for Economic Efficiency by Law:
„Wirtschaftlichkeitsgebot“

As always there is a need for economic efficiency: Wirtschaftlichkeitsgebot
§12 SGB V

§12 Wirtschaftlichkeitsgebot

(1) Die Leistungen müssen ausreichend, zweckmäßig und wirtschaftlich sein; sie dürfen das Maß des Notwendigen nicht überschreiten. Leistungen, die nicht notwendig oder unwirtschaftlich sind, können Versicherte nicht beanspruchen, dürfen die Leistungserbringer nicht bewirken und die Krankenkassen nicht bewilligen.

If there are various therapies of comparable efficiency lower cost drugs have to be prescribed.

Therefore documentation of therapies for each patient a must (labelling and guidelines to be acknowledged).
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Present Discussion

- Is HCV therapy too costly?
- Extra HCV Budget „Sonderausgabenvolumen for 2015 and 2016 approx. 1 Billion €
- Special contracts with Health Insurance Companies

- Treatment of „posttransfusion“ HCV patients (independent of fibrosis stage) is no problem in Germany.
- What about risk groups with high risk for re-infection and transmission?
German Hepatitis C Registry
Patient characteristics (30.6.2015) 5437 patients

Mode of transmission

- unknown: 45.1%
- IVDU: 15.6%
- Blood transfusion: 15.1%
- other: 24.2%

- OST: 604
- HIV-coinfected: 432
- Viral load >6 IU/ml: 557
Germany: How to improve access to HCV therapy

1. Guidelines and recommendations

2. Definition how and who should treat HCV: primary care physician versus specialized centers
Germany: How to improve access to HCV therapy

1. Guidelines and recommendations

2. Definition how and who should treat HCV: primary care physician versus specialized centers

3. Improved eligibility and tolerability of novel IFN free therapies:
   - Maasoumy et al Plos One 2013
   - Hoener zu Siederdissen et al Liv Int 2014
Germany: How to improve access to HCV therapy

1. Guidelines and recommendations

2. Definition how and who should treat HCV: primary care physician versus specialized centers

3. Improved eligibility and tolerability of novel IFN free therapies

4. Effective screening programmes !

5. Education networks for primary care physicians of OST patients and other risk groups
Screening is more important than SVR 90% versus 95%

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