Ledipasvir plus sofosbuvir: Hint of added benefit in certain patients

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The drug combination of ledipasvir and sofosbuvir (trade name Harvoni) has been available since November 2014 for the treatment of chronic hepatitis C infection. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether this new drug offers an added benefit over the appropriate comparator therapy.

IQWiG found a hint a non-quantifiable added benefit for two out of seven patient groups in total: in an infection with genotype 1 hepatitis C virus (HCV) when previous therapies had been unsuccessful, and when previously untreated patients have not yet developed cirrhosis of the liver. The data showed an advantage in sustained virologic response (SVR): Almost all patients were free of the virus after the Treatment.

Dossier only contained historical comparisons

IQWiG examined the added benefit separately for a total of seven patient groups, which were categorized according to genotype of the virus (1, 3, or 4), stage of the disease and previous treatment.

The drug manufacturer presented no direct comparative studies, but so-called historical comparisons. In a historical comparison, data from different studies, in which at least one of the treatments to be compared was tested, are compared.

At most hint possible

However, these kinds of results are susceptible to bias for several reasons. Conclusions on the (added) benefit can therefore generally only be derived when the effect differences are so large that they cannot be explained by the bias alone ("dramatic effect"). Due to the reduced certainty of conclusions, no more than a hint can be derived from these kinds of data, but no indication or even proof.

Genotype 1: almost all patients were free of the virus after treatment

For three patient groups with genotype 1, the manufacturer conducted a historical comparison from more than 20 studies in total, which showed a dramatic effect in the outcome "SVR": After treatment with ledipasvir and sofosbuvir, the virus was no longer detectable in almost 100% of the patients - treatment-experienced and treatment-naive patients with and without cirrhosis. In contrast, the success rate of the respective comparator therapies was only between nearly 35% and 75%.

The difference between the treatments was so large that an advantage of the new drug combination could be derived from it. It remained unclear, however, how large this difference is exactly because these were only historical comparisons.

It remained unclear how often liver cancer can be prevented

Greater harm in the form of side effects could not be excluded in treatment-naive patients with cirrhosis of the liver, however. IQWiG therefore found a hint of an added benefit only in two of the three genotype 1 groups, namely treatment-experienced and treatment-naive

patients without cirrhosis of the liver.

The extent of this added benefit is non-quantifiable, however. It remained unclear in how many patients in whom the virus is no longer detectable liver cancer can actually be prevented.

No added benefit for further patient groups

IQWiG found no added benefit of ledipasvir/sofosbuvir in any of the other four patient groups: The manufacturer dossier either contained no data (HCV genotype 4) or no comparative data (HCV genotype 3 and decompensated cirrhosis of the liver). For patients with genotype 1 HCV who are also infected with HIV, the manufacturer presented comparative data, but these were incomplete.

G-BA decides on the extent of added benefit

This dossier assessment is part of the early benefit assessment according to the Act on the Reform of the Market for Medicinal Products (AMNOG) supervised by the Federal Joint Committee (G-BA). After publication of the dossier assessment, the G-BA conducts a commenting procedure and makes a final decision on the extent of the added benefit.

More information: www.iqwig.de/download/A14-44_L … ertung_35a-SGB-V.pdf

Provided by Institute for Quality and Efficiency in Health Care

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