Remdesivir in COVID-19: Indication of considerable added benefit for some patients

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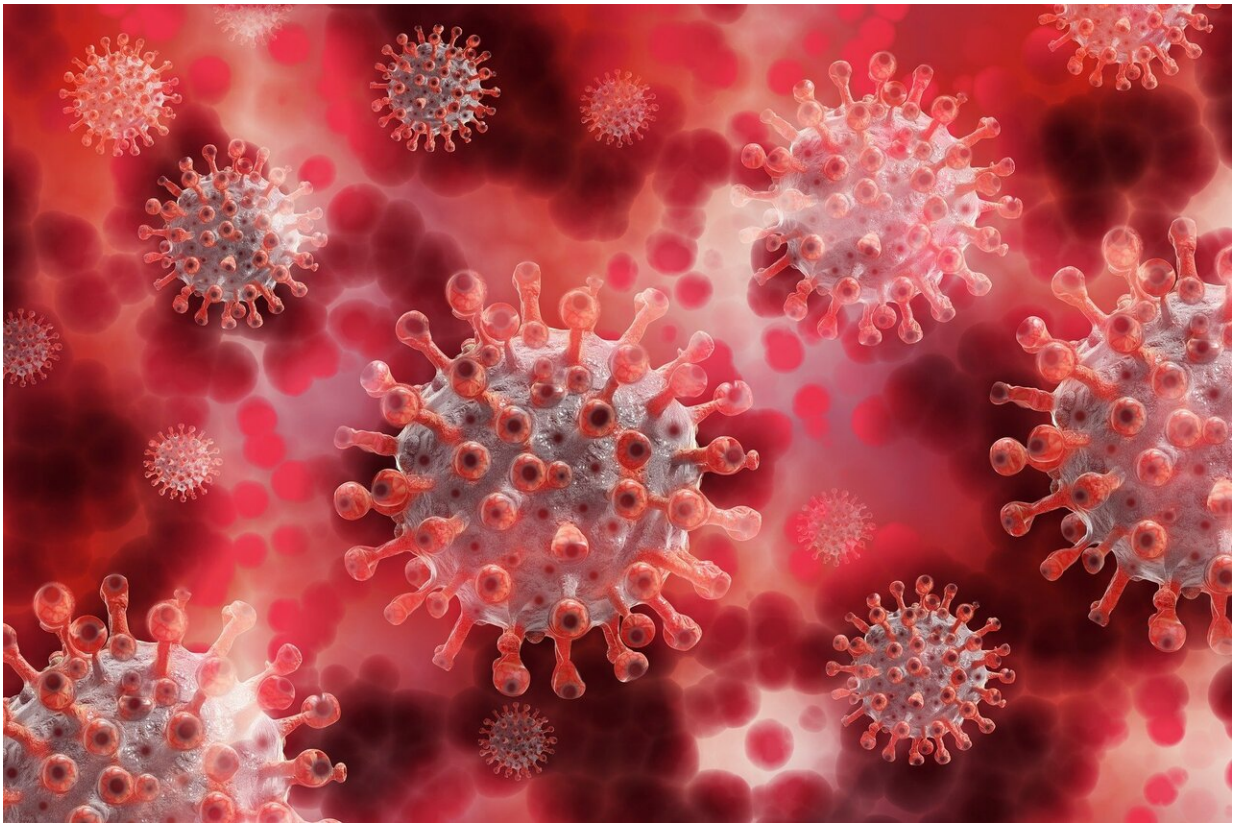

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Since July 2020, remdesivir has been conditionally approved in Europe for the treatment of coronavirus disease (COVID-19) in adults and adolescents aged 12 years and older with pneumonia who require

supplemental oxygen but no invasive ventilation. In an early benefit assessment, the German Institute for Quality and Efficiency in Health Care (IQWiG) has now investigated whether the drug, which was originally developed for the treatment of Ebola virus disease, offers these patients an added benefit compared to the appropriate comparator therapy.

This investigation yielded an indication of a considerable added benefit of remdesivir compared to the appropriate comparator therapy for adults with pneumonia who are moderately ill with COVID-19 and who 'only' received low-flow oxygen therapy at the start of treatment. However, an added benefit has not been proven for adults with more severe COVID-19 disease and pneumonia who already had to be treated with high-flow oxygen or other non-invasive ventilation at the start of treatment.

Study data for adolescents with COVID-19 disease were not available. As the mortality risks of this disease strongly depend on age, the results of the benefit assessment observed for adults cannot be transferred to adolescents either, so that an added benefit is not proven for this group.

Three RCTs conducted at the beginning of the Corona pandemic

The benefit assessment of remdesivir is based on the data from three randomized controlled trials (RCTs) with altogether 1,895 COVID-19 patients, from which subgroups with a total of 958 patients are relevant for the assessment. Patients in the comparator arm received treatment options currently available for diseases such as COVID-19.

In general, it can be assumed that the treatment of hospitalized patients with COVID-19 has improved since the beginning of the pandemic (e.g. administration of dexamethasone). Therefore, the treatment of

COVID-19 disease in the three studies included can only be transferred to the current care situation to a limited extent. This uncertainty was taken into account in the certainty of conclusions of the results.

Positive effects in moderately ill patients

For the subpopulation of adult COVID-19 patients with pneumonia and low-flow oxygen therapy at the start of treatment, the overall consideration shows predominantly positive effects of remdesivir compared to standard therapy: The affected individuals have a higher chance of survival and they recover more quickly. Although usable data on the side effects are lacking, the available information does not suggest any negative effects to an extent that could call an added benefit into question.

In summary, there is an indication of considerable added benefit of remdesivir versus the treatment according to physician's choice specified by the Federal Joint Committee (G-BA) as appropriate comparator therapy for adults with COVID-19 disease with pneumonia requiring low-flow oxygen therapy at the start of treatment.

Neither positive nor negative effects in patients with more severe disease

For the subpopulation of adults with COVID-19 disease with pneumonia and high-flow oxygen therapy at the start of treatment, the overall consideration shows neither positive nor negative effects of remdesivir compared with the treatment options available to date. An added benefit of remdesivir versus the appropriate comparator therapy can therefore not be derived for this group of patients with more severe COVID-19 disease.

Treating the right patients at the right time with

remdesivir

"Rarely has a new drug been so much in the focus of the global public as remdesivir at the beginning of the COVID-19 pandemic," says Thomas Kaiser, Head of IQWIG's Drug Assessment Department. "Today, almost exactly one year after the European Commission granted a conditional market approval, we know: COVID-19 patients with pneumonia who only need low-flow oxygen therapy at the start of treatment benefit considerably from treatment with remdesivir. However, the drug provides no benefit to patients with more severe disease. It is crucial to treat the right patients at the right time with the drug."

More information: Assesment (in German): www.g-ba.de/bewertungsverfahre … nutzenbewertung/671/

Provided by Institute for Quality and Efficiency in Health Care

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