Eidgenössische Kommission für Impffragen
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Schweizerische Gesellschaft für Infektiologie
Swiss Society for Infectious Diseases
Société Suisse d'Infectiologie

Current opinion on Evusheld (tixagevimab/cilgavimab) for the passive immunization treatment (pre-exposure prophylaxis) against SARS-CoV-2 in severely immunocompromised persons in Switzerland

Switzerland, 28 November 2022

This opinion statement is an addendum to the position paper of January 27, 2022 (version 26.04.2022, by the same expert working group), taking recent data and the current epidemiology as of 28 November 2022 into account. The official medical guidelines by the Swiss Society of Infectious Diseases (SSI/SGINF) are in agreement with the present document at the time of writing. Since the official SSI guidelines are regularly updated, this document or the position paper may deviate from the guidelines in the future.

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On 15th September 2022, Swissmedic approved the COVID-19 pre-exposure prophylaxis (PreP; "passive immunization") with the monoclonal SARS-CoV2-Spike antibodies tixagevimab and cilgavimab (Evusheld). Qualified physicians can prescribe Evusheld. The working group from the SSI and EKIF recommends administering Evusheld as PreP to subjects unable to mount an efficient immune response to COVID-19 vaccination (position paper on the use of monoclonal antibodies). These high-risk subjects include persons with a defined list of diagnoses or treatments (criteria list by the Swiss Society of Infectious Diseases). Exceptions can be considered based on a case-by-case evaluation. With the Swissmedic approval and the availability of Evusheld in Switzerland, the indication for PreP with Evusheld no longer has to be confirmed by an infectious disease specialist.

Because of changes in virus circulation and the ongoing fall booster vaccination campaign, the working group reevaluated the indications for PreP with Evusheld.
In vitro neutralization data indicates that tixagevimab / cilgavimab **may be less effective against newly emerging variants**, including BQ.1, and variants carrying a mutation on position 346. In Switzerland, the BQ.1 variant is increasingly identified in clinical samples, as are variants with the 346 mutation. In the absence of clinical effectiveness data of tixagevimab and cilgavimab against these variants, but in the absence of any other alternative PreP-option, we **currently still recommend using PreP in high-risk subjects with a documented failure to mount a significant antibody response after 1 or 2 booster doses of mRNA vaccines**.

We recommend using the higher dose of 300mg tixagevimab and 300mg cilgavimab for PreP to possibly improve the neutralization of omicron variants in this extremely fragile population of patients[1].

The COVID-19 vaccine booster results in a very high level of protection from severe COVID-19 in vaccinated subjects, including older adults. The working group, therefore, currently sees no good scientific rationale to extend the indication for passive immunization to other patients not belonging to the currently defined high-risk subjects. The working group also recommends continuing to use anti-Spike-IgG measurements to identify vaccinated subjects with non-response or inadequate response to vaccination among the high-risk group. There is currently no data available, which would suggest that subjects with a good immune response to COVID-19 vaccination have increased protection by passive immunization with Evusheld.

Because of the potentially reduced effectiveness of tixagevimab / cilgavimab against the new variants, other protective measures, including mask-wearing and hand hygiene, should be maintained and persons at risk should be tested and treated as early as possible in case they develop COVID-19 symptoms.

[1] This dose is higher than reported in the information for healthcare professionals of Evusheld and the phase III preventive trial.