Hellenic Republic
National Commission
for Bioethics & Technoethics

NATIONAL COMMISSION FOR BIOETHICS & TECHNOETHICS

RECOMMENDATION*

Patient prioritization regarding the disposal of therapeutic means against COVID-19 (monoclonal antibodies)

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NATIONAL COMMISION FOR BIOETHICS & TECHNOETHICS

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The NCBT discussed the issue of treatment prioritization for coronavirus, following a relevant request and accompanying note from the Ministry of Health.

The issue has occurred due to the availability of monoclonal antibody therapy in a limited number of doses, compared to the number of potential recipients among confirmed cases of the disease in the population.

It must be noted that the monoclonal antibody therapy is only suitable for the early stages of COVID-19, before the patient's possible hospitalization. This expands the circle of potential recipients in large groups of the population, which makes prioritization a particularly complex problem.

The Commission notes that, in principle, any therapy administration is subject to medical scientific criteria. Under this view, each particular case should be evaluated by the attending physician, on the basis of a risk /benefit analysis for the patient. When therapeutic means are not sufficient to cover the need of more patients, two possibilities occur: a) either medical criteria exclusively constitute a suitable basis to prioritize patients for receiving treatment, b) or to conclude that patients face an equal risk, therefore only medical criteria cannot support prioritization among them. In the latter case, prioritization should be based on ethical criteria also, and possibly on legal criteria (to the extent that specific legal regulation applies).

The Commission considers that, at present, access to monoclonal antibodies is necessarily subjected to this concern, as the mismatch of supply and potential demand remains significant.

PRINCIPLES

Bearing in mind the above remarks, the determination of priority criteria must refer to generally accepted principles of medical ethics. In particular, the following principles must be taken into consideration:

Protection of human life. According to this principle, all human beings have equal rights to life (equality), without any discrimination (biological, social, cultural, etc.). This means, that the social right to Health (article 21 para 3 of the Constitution) is equally recognized to everyone, as long as it supports the protection of life.

Beneficence. Following the beneficence principle, the administration of therapeutic means must be based on uncontested medical evidence, in order to ensure suitability, either for the complete recovery or for improving the patient's health.

Autonomy. Considering the autonomy principle, any medical act without the patient's free, prior and informed consent is forbidden. This justifies treatment refusal also, even if there is evidence that a specific act is for the patient's benefit.

Fairness. That principle requires a fair allocation of available health resources, depending on each person's special needs. In this context, policies supporting less privileged people and avoiding discrimination and exclusion must be in place. This is a criterion of "distributive justice", in accordance with equity (art. 4 para 1 of the Constitution).

Transparency. According to the transparency principle, access to the criteria and procedures of decision making regarding the allocation of health resources is required, as in the example of limited means for treatment.

PRIORITIZATION CRITERIA

Based on the above-mentioned principles, the Commission:

- *Recognizes* that those in higher risk of serious disease should be given priority.

-*Suggests* using the treatment only in those cases that it is expected to be beneficial to the person's health and not as a means of "prevention after exposure" ("post-exposure prophylaxis"), provided that prior and informed consent has been given by the patient or (when unable to consent) by their legal representatives.

-*Notes* that risk assessment should take into consideration the severity and proximity of risk due to underlying diseases (see ANNEX) and should be based on generally accepted factors (scientific data of COVID-19), such as the age, the immunosuppression level, and the comorbidities. The presence of more than one of the above factors multiplies the risk of serious disease, and for that reason it can be considered a priority criterion.

-*Suggests* to take into account evaluation indicators and numerical values to risk factors.

-*Suggests,* whenever possible, to take into consideration measurable adverse social and economic factors that potentially make certain categories of patients vulnerable (if not receiving treatment), in order to avoid aggravation of inequalities[1].

[1] See https://www.sciencedirect.com/science/article/pii/S0012369221036229

PROCEDURE

According to the Commission, the State must refer to the above-mentioned criteria in all its decisions regarding the attribution of the specific treatment.

The risk assessment criterion may be further developed, after an urgent consultation process with medical and patient associations, aiming at the greatest possible clarity. The criterion must be publicly known. A permanent mechanism for adapting specific details must be established, based on the experience gained and the availability of treatment.

The Commission considers the creation of a "Central Committee for the Evaluation of Attending Physicians' Requests" as an appropriate means that may contribute to the equal access to treatment. A "within 24 hours" response of that organ, as planned, is important being necessary for ensuring the intervention's effectiveness.

Finally, special care needs to be taken to ensure that patients from all regions of the country, central and remote, will have equal access to monoclonal antibodies.

ANNEX

Prioritization Criteria regarding the disposal of monoclonal antibodies

Patients that may be eligible for the monoclonal antibody therapy, are adults or children (aged 12 years and older and ≥ 40 kg) outpatients, found to be positive in COVID-19, with mild to moderate COVID-19 symptoms in the last 5 days, being at high risk of aggravation of their condition, with the following factors of high risk:

High risk diseases		ICD 10
Transplantation	Solid organ transplantation or hematopoietic stem cell transplantation	Z94, T86
	Persons in the waiting list for organ transplant	

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Renal failure	Hemodialysis or peritoneal dialysis	N18, N19, Y84.1
	Cystic fibrosis	E84
Cancer under treatment	People with solid organ cancer subjected to therapy (chemotherapy, radiotherapy, immunotherapy, or other therapy) *	C00 – 97 (does not apply to blood cancers)
	Hematologic malignancies in the last year**	D37 - D48, C81 - C86, C88, C90 - C95
Patients with primary immunodeficiencies & secondary immunodeficiencies due to treatment with B-special factors e.g. Rituximab		D80-D84
HIV with CD4≤200 cells/mL		
Third trimester pregnancy		Z32.1
On epidemic outbreaks in elderly care units		
**people who are subjected to therapy for cancer from 1/11/2020* ***people who have been diagnosed with blood cancer from 1/11/2020*		

Regarding the above patients, there is possibility of considering co-existing conditions leading to increased risk of serious disease such as:

- Age ≥ 65 years, BMI> 40, Other serious comorbidities such as chronic kidney disease, unregulated diabetes (with glycosylated hemoglobin> 9).

Furthermore, considering the experience of vaccine distribution, the following are also suggested:

- Central distribution of monoclonal antibodies.

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- Administration by health units not having a large burden on arriving patients in ICUs following a scheduled appointment procedure.
- Establishment of a central Committee for the evaluation of requests made by treating physicians within 24 hours.
- Creation of a platform for managing the requests of treating physicians, following appropriate parameterization for the evaluation of them by the above Committee (upon necessary adjustments in parameterization, it is also suitable the platform that has been used for prioritization in vulnerable groups' vaccinations, given that it concerns high-risk patients similarly to the patients considered for the administration of monoclonal antibodies).