

Prague, February 2021  
Ref. No. MZDR 3724/2021-3/OBP  
**IHHIIMIUIíniNIIIIU**  
MZDRX01EDOAG

## DECISION

The Ministry of Health (hereinafter referred to as the “Ministry”), as the competent administrative authority pursuant to Section 11(a) of Act No. 378/2007 Coll., on pharmaceuticals and on the amendment of certain related laws (hereinafter referred to as the “Act on Pharmaceuticals”), as amended, has decided on the following measure:

In the interest of protecting public health in relation to the currently ongoing global COVID-19 pandemic caused by the spread of the SARS-CoV-2 virus, and in order to ensure the availability of medicinal products important to providing medical care, the Ministry, in accordance with Section 8(6) of the Act on Pharmaceuticals,

### temporarily permits

the distribution, dispensing and use of the non-registered human medicinal product **Bamlanivimab (LY-CoV-555, formerly LY3819253), concentrate for infusion solution, 700 mg**, which contains 700 mg of the medicinal substance *bamlanivimab* in 20 ml solution (concentration 35 mg/ml) in an injection vial (hereinafter the “medicinal product BAMLANIVIMAB”).

Number of packages: 12 400.

The dispensing of the medicinal product BAMLANIVIMAB requires a doctor’s prescription.

The following conditions must be fulfilled for the distribution, dispensing and use of the medicinal product BAMLANIVIMAB:

1. The medicinal product BAMLANIVIMAB is designed to treat patients with COVID-19 who are more than 12 years of age, with a body weight of at least 40 kg, whose clinical condition is deemed to be mild, not requiring hospitalisation or the therapeutic application of oxygen, provided that the duration of clinical symptoms does not exceed 7 days and the period from determining the positivity of a test for SARS-CoV-2 does not exceed 3 days, and there is a high risk that the patient’s clinical condition will worsen.

The characterization of a patient with a high risk includes at least one of the following criteria:

- condition after transplantation of a solid organ or bone marrow transplant,<sup>g</sup>

- vasculitis with currently ongoing combined immunosuppressive treatment or monotherapy using corticosteroids,
  - oncological or hemato-oncological disease with currently ongoing treatment,
  - pulmonary hypertension in dispensary care,
  - chronic renal insufficiency in a regular dialysis program,
  - BMI higher than 40,
  - chronic obstructive disease in stage GOLD III and IV (in stage GOLD IV only for patients who do not require domestic oxygen treatment), interstitial pulmonary disease in dispensary care, bronchial asthma under biological treatment,
  - thrombophilic condition in dispensary care.
2. The medicinal product BAMLANIVIMAB may only be administered to the patient on the basis of an electronic request form submitted via the Information System of Infectious Diseases (ISIN), or equivalent thereof, in which the indicating physician specifies all the required information including risk criteria.
  3. The medicinal product BAMLANIVIMAB may only be administered to the patient by an inpatient healthcare services provider with type I or type II urgent admission, specified in the list published on the Ministry's website. The patient must be monitored during the administration of the medicinal product BAMLANIVIMAB and for at least 1 hour after infusion.
  4. The physician administering the medicinal product BAMLANIVIMAB is obliged:
    - to become familiar with the Instructions for preparation and handling and to proceed accordingly,
    - to inform the patient that they will be treated with a non-registered medicinal product and to familiarize them with the benefits and risks of treatment,
    - to enter the administration of the medicinal product BAMLANIVIMAB and complete all the required data in the Information System of Infectious Diseases (ISIN) or equivalent thereof,
    - to report any adverse effects which occur in connection with administering the medicinal product BAMLANIVIMAB via the web interface of the State Institute for Drug Control: [www.sukl.cz](http://www.sukl.cz) - Report for SÚKL / Report of suspected adverse effect of a medicinal product.
  5. The healthcare services provider is obliged to ensure the handover of the printed Patient Information for the medicinal product BAMLANIVIMAB in the Czech language (hereinafter the "Patient Information") to the patient and the signing of informed consent by the patient (or their authorized representative) to the administration of the non-registered medicinal product BAMLANIVIMAB.
  6. Distribution of the medicinal product BAMLANIVIMAB to the Czech Republic is ensured by Movianto Deutschland GmbH, In der Vogelsbach 1, Neunkirchen, Saarland, 66540, Germany (hereinafter the "distributor Movianto Deutschland GmbH"), to the pharmacy of Thomayer University Hospital, Vídeňská 800, 140 59 Prague 4 - Krč (hereinafter the "coordinating pharmacy"). The distributor is obliged to inform the State Institute for Drug Control about the start of the distribution activity in the Czech Republic based on a permit to distribute the medicinal product, issued by another European Union member state (DIS-10).
  7. The distributor is obliged to inform the State Institute for Drug Control about the performed deliveries

of the medicinal product BAMLANIVIMAB to the coordinating pharmacy at latest within 48 hours from delivery of the product, via [marketreport@sukl.cz](mailto:marketreport@sukl.cz). The report will include information about the date of delivery, form of medication, number of product packages and batch of the medicinal product BAMLANIVIMAB.

8. The coordinating pharmacy will provide the medicinal product BAMLANIVIMAB to the pharmacy of the healthcare service provider pursuant to point 3 based on a request form. The coordinating pharmacy is obliged to report information about the provided packages of the medicinal product BAMLANIVIMAB to the State Institute for Drug Control via e-mail [marketreport@sukl.cz](mailto:marketreport@sukl.cz) at latest within 24 hours from sending.
9. Before commencing distribution to the Czech Republic, the company Eli Lilly ČR, s.r.o., registered office at Pobřežní 394/12, 186 00 Prague 8, Company ID No. 649 41 132 (hereinafter “Eli Lilly”), will submit the complete production chain for the medicinal product BAMLANIVIMAB to the State Institute for Drug Control.
10. Eli Lilly shall ensure
  - access to the Instructions for preparation and handling of the medicinal product BAMLANIVIMAB in the Czech language (hereinafter “Instructions for preparation and handling”) via a QR code to healthcare professionals,
  - delivery of the printed Patient Information to the coordinating pharmacy.
11. The coordinating pharmacy is obliged to ensure the handover of the printed Patient Information when providing the medicinal product BAMLANIVIMAB to the healthcare service provider’s pharmacy pursuant to point 3.

**This measure is effective until 30 April 2021.**

#### **Rationale:**

On 2 February 2021, the Ministry received a request from Eli Lilly to permit the distribution, dispensing and use of the non-registered human medicinal product BAMLANIVIMAB - a neutralizing antibody treatment for COVID-19 based on Section 8(6) of the Act on Pharmaceuticals.

On 2 February 2021, the Ministry requested an expert opinion from the State Institute for Drug Control (hereinafter the “Institute”) pursuant to Section 8(6) of the Act on Pharmaceuticals regarding the temporary permission of the distribution, dispensing and use of the non-registered medicinal product BAMLANIVIMAB, for the treatment of patients with COVID-19.

On 8 February 2021, the Ministry received the Institute’s expert opinion Ref. No. suk135544/2021 of 5 February 2021 on the requested matter (hereinafter the “Institute’s opinion”). In its opinion, the Institute stated that the medicinal product BAMLANIVIMAB is not registered in any country, and is currently approved for use within EUA (Emergency Use Authorisation) in the USA, within a similar regime in Canada, and based on the decision of the Ministry of Health in Germany. *Bamlanivimab* (LY-CoV555; LY3819253) and the other monoclonal antibody *etesivimab* (LYC0VOI6; LY3832479) are also in the process of Scientific Advice with the European Medicines Agency (EMA).

Regarding the assessment of quality, the Institute stated that because the medicinal product BAMLANIVIMAB was permitted in the USA within EUA (Emergency Use Authorisation), and because a MRA (Mutual Recognition Agreement) has been concluded between the USA and EU, and also because it is being released by an entity based in the EU, it considers the proof of adequacy of production locations to be sufficient for the purpose of granting an exception. However, the Institute recommended that the Ministry of Health stipulate in its decision the obligation of Eli Lilly to specify the complete production chain. The Institute evaluated the pre-clinical (non-clinical) data submitted by Eli Lilly and stated that the toxicological profile of *bamlanivimab* is favourable and the safety is sufficient to allow the use of the medicinal product BAMLANIVIMAB for emergency use.

The Institute also stated that due to the limited supplies, the labelling of the external packaging and injection vial is only in English and the package leaflet is not a part of the packaging of the medicinal product BAMLANIVIMAB. The Institute agrees to the distribution of the package leaflet and Instructions for preparation and handling via a QR code for healthcare professionals, and proposes that the patient be provided with information about the product in printed form in the Czech language.

Because this concerns the use of a non-registered medical product, the Institute recommended to the Ministry to stipulate an obligation in the decision for physicians to observe the Instructions for preparation and use when handling the medicinal product BAMLANIVIMAB, and with respect to the specific nature of the situation and protection of public health, to report any adverse effects via the Institute's website.

V In the part concerning the assurance of distribution, the Institute stated that the importer to the EU will be the company ELECTS, Belgium (CT Group). Deliveries to the Czech Republic will subsequently be carried out via the distributor Movianto Deutschland GmbH. Because the distributor Movianto Deutschland GmbH is not among the distributors approved by the Institute, the Institute proposed that the Ministry stipulate in its decision the obligation of Movianto Deutschland GmbH to notify the commencement of distribution activity in the Czech Republic based on a permit to distribute a medicinal product issued in another EU member state (DIS-10). The distributor Movianto Deutschland GmbH is obliged to observe the provisions of the Act on Pharmaceuticals, and any other obligations stipulated in the Ministry of Health's decision. The Institute recommended that the Ministry also stipulate the distributor's obligation to inform the Institute of performed deliveries to healthcare facilities at the latest within 48 hours to the address [marketreport@sukl.cz](mailto:marketreport@sukl.cz), with a specification of the date, number of packages, batch and healthcare facility to which the medicinal product BAMLANIVIMAB was delivered.

V In the part regarding ensuring dispensing and use, the Institute stated that the medicinal product BAMLANIVIMAB shall be delivered to the coordinating pharmacy of Thomayer University Hospital, which shall ensure delivery to other healthcare service providers. The coordinating pharmacy is obliged to report information about the provided packages of the medicinal product to the Institute via e-mail to [marketreport@sukl.cz](mailto:marketreport@sukl.cz) at the latest within 24 hours from sending.

The Institute stated that the medicinal product BAMLANIVIMAB should be designated to treat mild to moderate cases of COVID-19. The benefits of treatment among patients hospitalised with COVID-19 has not been observed. The administration of monoclonal antibodies to patients hospitalised with COVID-19 may be associated with worsened clinical results. Likewise, there is no data except for experimental use in combination with the other as yet non-registered monoclonal antibody *etesivimab* (LY-C0VOI6), which would prove the benefits of treatment using *bamlanivimab* in combination with other antibodies. The Institute also stated that it has no information about potential interactions between the medicinal product BAMLANIVIMAB and other medicinal products used to treat COVID-19 (Veklury, Fortecortin, Isoprinosine) in the case of simultaneous administration.

Furthermore, the Institute proposed that the Ministry, in its decision, take into account whether the medicinal product BAMLANIVIMAB can be administered only by healthcare services providers equipped with resources to commence the immediate treatment of severe reactions after infusion, such as anaphylactic shock, and with ensured anesthesiological-resuscitation care. The patient must be monitored during the administration and for at least 1 hour after the infusion.

V In the conclusion of its opinion, the Institute stated that, given the fact that it is a medicinal product which does not have any alternative on the Czech market and it is a matter of procuring a medicinal product for the potential prevention of serious medical condition, it agrees to the granting of an exemption to permit the use of the non-registered medicinal product BAMLANIVIMAB while observing the conditions set forth in the Institute's opinion and considering the benefits for the defined group of high-risk outpatient patients with confirmed SARS-CoV-2 infections, provided that the limited data about the efficacy of the respective indication and dose (700 mg) are taken into account. When handling this medicinal product, it is necessary to observe the provisions of the Act on Pharmaceuticals, with the exception of the specified particularities.

Upon assessment of the expert references and given the opinion of the Institute, the Ministry states the following:

V in connection with the incidence of the COVID-19 disease caused by SARS-CoV-2 coronavirus, it is necessary to ensure the availability of the medicinal product BAMLANIVIMAB for patients in the Czech Republic, which is designated for patients with COVID-19 whose clinical condition was evaluated as mild, but who are at a high risk of progression into a severe form of COVID-19 and/or hospitalisation.

The specification of patients to whom the medicinal product BAMLANIVIMAB may be administered is based on the inter-departmental opinion of the Czech Society for Anesthesiology, Resuscitation and Intensive Medicine (ČSARIM) of ČLS JEP, the Czech Society for Intensive Medicine (ČSIM) of ČLS JEP, the Society for Infectious Medicine (SIL) of ČLS JEP, the Czech Pneumology and Phthisiology Society (ČPFS) of ČLS JEP and the Association of General Practitioners for the use of bamlanivimab among patients with COVID-19, Reg. No. ČSARIM: 15/2021, which is published on the websites of the listed expert societies, i.e., [www.csarim.cz](http://www.csarim.cz).

The conditions stated in the decision were stipulated by the Ministry based on the recommendations set forth in the Institute's opinion, in order to ensure the safety of the used medicinal product BAMLANIVIMAB, in particular because this medicinal product is not registered in any country and only limited data exists about its safety and the efficacy of its use. For this reason, physicians are obliged to report any adverse effects to the Institute and to cooperate in monitoring clinical data to allow the evaluation of the efficacy and safety of the medicinal product BAMLANIVIMAB.

In accordance with the request from Eli Lilly and the opinion of the Institute, the Ministry decided that the medicinal product BAMLANIVIMAB shall only be distributed to the coordinating pharmacy that, in accordance with Section 82(4) of the Act on Pharmaceuticals, will provide the medicinal product BAMLANIVIMAB to the inpatient healthcare service providers with type I and type II urgent admission that are specified in the list published on the Ministry's website. At these workplaces, the medicinal product BAMLANIVIMAB will be administered based on an electronic request form completed by the indicating physician, who evaluated that the patient is at high risk of a worsened clinical condition in connection to the confirmed COVID-19 disease, and the patient meets the indication criteria defined in the inter-department opinion of the expert societies of ČLS JEP.

Given the fact that this is a medicinal product which has no alternative on the market in the Czech Republic, and the matter concerns the procurement of a medicinal product to potentially prevent

serious health conditions, the Ministry temporarily permits the distribution, dispensing and use of the medicinal product BAMLANIVIMAB, while fulfilling the conditions specified above, for a period until 30 April 2021, which corresponds to the time needed to evaluate the clinical experience with the use of the medicinal products BAMLANIVIMAB. When handling this medicinal product, it is necessary to observe the provisions of the Act on Pharmaceuticals, with the exception of the foregoing particularities.



**doc.MUDr. Jan Blatný, Ph.D.,**  
Minister of Health

**Authorised conversion clause to the document contained in the data message**

This document, which was created by converting a paper entry into electronic form under the order number 135811379-316335210211090438, consisting of 3 sheets, is literally identical to the content of the entry.

The authorised conversion of the document does not confirm the accuracy and truthfulness of the data contained in the document and their compliance with legal regulations.

**Security element:**

no security element

**Entity performing authorised document conversion:**

Ministry of Health of the Czech Republic

**Date of issuing clause:**

11.2.2021

**Name, surname and signature of person performing authorised document conversion:**

Marcela Bendigová



135811379-316335-210211090438

---

**Note:**

*This clause can be checked in the central clause records accessible via means enabling remote access at the address <https://www.czechpoint.cz/overovacidolozky>.*