Anti-rabies virus monoclonal antibodies

Essential medicine status

Section: 19. Immunologicals > 19.2. Immunologicals > Sera, immunoglobulins and monoclonal antibodies

EMLc | ATC codes: Pending

Indication	Rabies ICD11 code: 1C82
Medicine type	Biological agent
List type	Core (EML) Complementary (EMLc)
Additional notes	Including quality-assured biosimilars
Formulations	Parenteral > Locoregional injections > Intradermal: 40 IU per mL in 1.25 mL vial (human) ; 40 IU per mL in 2.5 mL vial (human) ; 100 IU per mL in 2.5 mL vial (human) ; 300 IU per mL in 10 mL vial (murine) ; 600 IU per mL in 1 mL vial (murine) ; 600 IU per mL in 2.5 mL vial (murine) ; 600 IU per mL in 5 mL vial (murine)
EML status history	First added in 2021
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Read more about patents.
Tags	Biosimilar
Wikipedia	Anti-rabies virus monoclonal antibodies

Expert Committee recommendation

The Expert Committee acknowledged the public health need for effective interventions for rabies postexposure prophylaxis, noting that the case fatality of rabies infection is almost 100% after the onset of clinical symptoms. The Committee considered that the availability of a range of alternative options for use in rabies postexposure prophylaxis (human RIG, equine RIG and ARV mAbs) on the EML and EMLc would facilitate access to treatment. The inclusion of ARV mAbs will potentially address some of the supply and production limitations currently experienced with hRIG and eRIG by increasing procurement options. It was also noted that ARV mAbs could be procured at lower cost than human RIG (but higher cost than equine RIG). The Committee noted that the clinical evidence supporting the use of ARV mAbs is from trials assessing rabies virus neutralizing activity, using an in vitro correlate of protection that has been accepted by WHO and regulatory agencies as a study endpoint in clinical trials of novel rabies vaccines or RIG products. The Committee also noted that there was no indication of an increase in mortality from postmarketing surveillance. The Committee acknowledged that evidence on efficacy and safety for use in children, the elderly or pregnant women was lacking, but was reassured by the technical unit that children were included in the trial populations, however the data had not yet been stratified. Moreover, the Strategic Advisory Group of Experts (SAGE) on Immunization recommended postmarketing surveillance of these products due to their potential adverse effects. The Committee noted that the 2018 WHO position paper on rabies encourages the use of ARV mAbs as an alternative to RIG and that having access to RIG and ARV mAbs may ensure adequate supply at the global level. The Committee also noted that WHO prequalification processes for monoclonal antibodies for infectious diseases are planned in 2022, to facilitate access to affordable and quality-assured products. Therefore, the Expert Committee recommended the inclusion of ARV mAbs (murine and human formulations), including quality-assured biosimilars, on the core list of the EML and EMLc for use as part of rabies postexposure prophylaxis, in line with WHO recommendations.