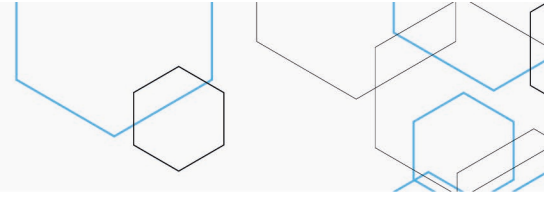


Human anti-hepatitis B immunoglobulin 1,000 IU

Brasília – DF
2020



Technology: Human anti-hepatitis B immunoglobulin 1,000 IU.

Indication: Prophylaxis of hepatitis B virus reinfection after liver transplantation.

Applicant: Secretariat of Science, Technology and Strategic Inputs (SCTIE/Ministry of Health of Brazil).

Context: Chronic hepatitis B virus (HBV) infection is a major global health problem, which affects an estimated 350 million people worldwide, and up to 786,000 deaths annually are associated with related complications. Liver transplantation (LT) is considered the gold standard for the treatment of HBV-related liver failure and hepatocellular carcinoma. However, post-LT viral reactivation can affect the allograft function, leading to poor survival and representing a great challenge to clinical practice. The prophylaxis of HBV reinfection after liver transplantation is recommended in the Clinical Protocol and Therapeutic Guidelines of the Ministry of Health of Brazil, with the use of lamivudine and human anti-hepatitis B immunoglobulin 800 IU per day during a significant part of the treatment period.

Justification of the request: Currently, to obtain the indicated dose, it is necessary a vial containing 600 IU or 500 IU of human anti-hepatitis B immunoglobulin together with vials of 100 IU. However, due to contractual issues with the manufacturer, the General Coordination of the Specialized Component of Pharmaceutical Assistance (Department of Pharmaceutical Assistance and Strategic Inputs/Secretariat of Science, Technology and Strategic Inputs/Ministry of Health of Brazil) should deliver the 1,000 IU presentation, on an exceptional basis, even though this presentation is not included in the National Relation of Essential Medicines (RENAME in Portuguese). Therefore, despite human anti-hepatitis B immunoglobulin is already available in the Brazilian Public Health System (SUS), it has been requested the inclusion of its 1,000 IU presentation.

Final Recommendation: The members of CONITEC's plenary session present at the 87th Ordinary Meeting, on June 3rd and 4th, 2020, unanimously decided to recommend the incorporation of human anti-hepatitis B immunoglobulin 1,000 IU, in the scope of SUS. The Deliberation Record No. 524/2020 was signed.

Decision: To incorporate human anti-hepatitis B immunoglobulin 1,000 IU, in the scope of SUS, according to Ordinance No. 30, published in the Official Gazette of the Federal Executive No. 160, Section 1, page 118, on August 20th, 2020

