Results: In 2016, pembrolizumab was granted registration in Brazil was restricted to patients with advanced melanoma. In 2022 the indication was expanded to more than 20 new indications, with several studies in progress that potentially will lead to further inclusions. The estimate of patients eligible for indications increase of 1,796 to 99,544 patients with an increased total cost from BRL625,802,837 to BRL34,685,366,192 (USD121,185,677.4 to USD6,716,763,399.04).
Conclusions: The financial burden of pembrolizumab's expanded uses after it was first approved could significantly rise, endangering the long-term viability of healthcare systems. In Brazil, where medicine costs are not regularly monitored, the annual inflation adjustment is the only factor that causes prices to change. In order to lower medicine prices in response to the addition of new indications, the expansion of therapeutic options for the same condition, or even obsolescence, regulations are required.

PP105 Efficacy, Effectiveness And Safety Of Letermovir For Prophylaxis Of Cytomegalovirus Infection And Disease Post-Allogeneic Hematopoietic Stem Cell Transplantation

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Introduction: Clinically significant cytomegalovirus infection (CSI-CMV) is an important factor associated with mortality in patients undergoing hematopoietic stem cell transplantation (HSCT). It is estimated that the incidence of CSI-CMV in the post-HSCT period is 30 percent to 70 percent in transplanted individuals. Therefore, CSI-CMV is considered a complication in allogeneic HSCT, which can trigger Cytomegalovirus disease (CMVD). Letermovir is an antiviral agent indicated especially for the prophylaxis of CMVD post-HSCT. The objective of this work was to evaluate the efficacy, effectiveness and safety of letermovir, comparing it with placebo or other existing prophylactic treatments.
Methods: A systematic review was carried out according to PRISMA 2020. A strategy was developed for searching electronic bibliographic databases. Retrieved publications were selected by a pair of reviewers. The same pair performed the data extraction. A qualitative assessment of the efficacy, effectiveness and safety of letermovir was performed.
Results: Eighteen studies were included, being experimental and observational. Overall, the pivotal RCT demonstrates the efficacy of letermovir in reducing the incidence of CSI-CMV. However, there was no statistically significant difference in all-cause mortality and letermovir-related overall survival, events of graft versus host disease, neutropenia, acute kidney disease and 48-week mortality. Observational studies, in general, present results similar to those found in the pivotal RCT. The main adverse events associated with letermovir were peripheral edema (14.5%), vomiting (18.5%), headache (13.9%), cough (14.2%), abdominal pain (11.8%) and fatigue (13.4%).
Conclusions: The prophylactic use of letermovir in CMV-R+ patients after allogeneic HSCT demonstrates beneficial results in the prevention of CSI-CMV. However, there were no identified improvements for other outcomes. As for safety, it was observed that there is still little information about adverse events related to the drug, and studies assessing this aspect are needed for better comprehension.

PP106 Integrating Organizational Impacts Into Health Technology Assessment: How To Take Them Into Account For Medical Devices?

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Introduction: The organizational impact (OI) of new technologies is becoming a major driver for our healthcare systems and for modernizing the care pathway for the benefit of users and professionals. Some technologies give rise to a reorganization of the healthcare system, particularly in the case of connected medical devices.
The Medical Device Committee at Haute Autorité de Santé (HAS) appraises medical devices (MD) in view of their reimbursement by the French health insurance scheme. The Committee's evaluation criteria take account of the therapeutic benefit of the MD and its public health benefit. OI-related aspects are frequently claimed by health technology developers (HTD) in their MD submission dossiers. However, this aspect is rarely documented. Therefore, guidance explaining how HTD should support and structure any claim of an OI was needed.
Methods: This work was based on the HAS OI Map for Health Technology Assessment published in 2020, the analyses of specific HAS opinions, hearings with concerned stakeholders (HTD, service providers and patients), and a committee meeting focused on OI.
Results: The HTD guide for MD submission was updated with guidance to support OI claims. For each claimed OI, the HTD should identify the criterion corresponding to the most relevant OI, the indicator to describe each selected criterion, the stakeholders concerned, and the data to be provided. The choice of method is according to the OI: if the indicator is measurable, data from validated measurement tools are expected. If not, especially in cases where the use of the MD requires a specific organization before its deployment, the absence of data must be justified and a detailed impact

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