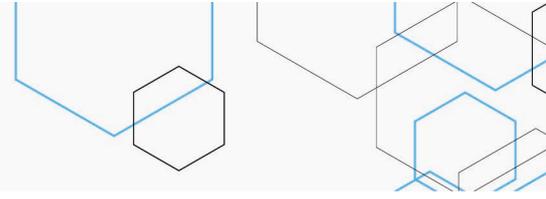


# Increasing the upper age limit to 75 years for allogeneic Haematopoietic Stem Cell Transplantation (HSCT) procedures



**Technology:** Allogeneic Haematopoietic Stem Cell Transplantation (HSCT).

**Request:** To increase the upper age limit to 75 years for allogeneic HSCT procedures.

**Applicant:** Secretariat of Specialized Health Care (Ministry of Health of Brazil).

**Background:** Haematological diseases, especially those affecting the myeloid lineage, are more prevalent in individuals over the age of 60 years. Haematopoietic Stem Cell Transplantation (HSCT) is a therapeutic modality used in the treatment of numerous blood disorders, which may be benign or malignant, inherited or acquired. Allogeneic HSCT involves the replacement of diseased bone marrow with healthy bone marrow cells from a parent or an unrelated donor for the purpose of reconstituting haematopoiesis. It is being increasingly used due to greater experience and improvement of the technique, development of new and less aggressive immunosuppressive drugs and regimens, as well as advancement in the treatment of post-transplant complications. Since mid-2006, it is indicated worldwide not only for new diseases, but especially for patients over 60 years of age. In Brazil, where life expectancy at birth is 72 years for males and 79 for females, the treatment of patients over 60 with hematologic malignancies involves only chemotherapy, as the upper age limit for HSCT procedures is 60 years. However, with the improvement in the living conditions of the population in the last two decades, directly impacting life expectancy, allogeneic HSCT may be performed more safely in patients over 60 years of age.

**Justification of the request:** Although the worldwide literature indicates that allogeneic HSCT can be performed safely in elderly patients for the treatment of hematologic malignancies, the Brazilian Ministry of Health Consolidation Ordinance No. 04, from September 28th, 2017, sets that the upper age limit for allogeneic HSCT procedures is 60 (unrelated allogeneic HSCT) and 65 years (related allogeneic HSCT). Therefore, this Ordinance is out of date compared to the recommendations of several medical societies worldwide, including the Brazilian Society of Bone Marrow Transplantation. It prevents patients above the upper age limit who, except for a malignant disease of the blood, are in relatively good health in terms of physiological, psychological, nutritional, neurological, and social factors and criteria, from receiving curative treatment (HSCT). This treatment could increase their overall survival by at least 3 years, reaching up to 15 years, if there is no recurrence, and in case of mild graft-versus-host disease (GVHD) (grades I or II). With the new immunosuppressive drugs and regimens for both pre- and post-transplant procedures, as well as the development of sensitive and specific techniques that improve compatibility of donor and recipient, and safety of transplantation, the allogeneic HSCT for patients over 60 years has become an excellent option for curative treatment of hematologic malignancies. Moreover, due to the increase in the population's quality of life and life expectancy at birth, age alone is no longer considered a risk factor for transplantation. Therefore, the recommendation to use the "Comprehensive Geriatric Assessment (CGA)" – an instrument to assess the medical, psychological, cognitive, nutritional, and social status, together with the standard pre-HSCT evaluation already performed in patients with hematologic malignancies – allows patients over 60 years with these conditions to benefit from allogeneic HSCT as a curative treatment, since the chronological age alone is no longer a contraindication.

**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 increase of the upper age limit to 75 years for allogeneic Haematopoietic Stem Cell Transplantation (HSCT) procedures, in the scope of the Brazilian Public Health System (SUS). The Deliberation Record No. 525/2020 was signed.

**Decision:** To increase the upper age limit to 75 years for allogeneic Haematopoietic Stem Cell transplantation (HSCT) procedures, in the scope of SUS, according to Ordinance No. 29, published in the Official Gazette of the Federal Executive No. 160, Section 1, page 117, on August 20th, 2020.

