newsletter

Stem cells from cord blood

Over the last two years, the global cord blood industry has seen double-digit rates of growth. At present, over 220 private and around 100 public registered cord blood banks are storing more than 1 million units and will continue to store them for decades. Correspondingly, there is an increasing need for bespoke insurance solutions in this line of business.

Stem cells

Stem cells are the general progenitors of all hematopoietic cells that continually generate red and white blood cells and blood platelets in the bone marrow. They can be isolated and transferred to a recipient. This is the basis for the transplantation of bone marrow and peripheral blood stem cells to treat serious blood disorders, a process which has been successful for the last 25 years. Donated cord blood has become a further reliable source of stem cells over the last ten years, and it is therefore a valuable biological resource. Annual transplant numbers have risen over the last ten years from just a few hundred to a total of over 4.500 in 2010.
Around 25% of cord blood stem cell transplants performed each year are carried out on patients under the age of 20. Around the world more than 22.000 cord blood units (CBU) have been transplanted, most of which come from public cord blood banks. By 2015 this is set to rise to 10.000 units per year.

Advantages, indications

Cord blood stem cells are easy to harvest, they can be frozen for decades, are less likely to be rejected than bone marrow transplants, and carry a lower infection risk. They also widen the availability of transplant options, particularly for patients from ethnic minorities or who have unusual tissue types.
At present there are over 70 indications for the use of CBUs, including diseases of the blood-forming or lymphatic systems, metabolic disorders, genetic defects, immunodeficiencies and tumours.

Cord blood banks

The establishment of cord blood banks that can offer the necessary storage facilities (monitored tanks of liquid nitrogen), logistics and administration was key to the success of CBU transplantation. Since a number of governments decided in 2005 to provide financial support for the storage of CBUs in order to increase their availability, this source of stem cells has attracted increased attention. New cord blood banks have sprung up as a result, particularly those which are privately operated.

- Private commercial banks offer storage of cord blood for the personal use of the donor and their family in return for payment (autologous donation). Average costs at present are around USD 1.500 for testing, processing and storage, and an additional USD 100 per year for continued storage. Typically the child or their parents have right of access to the transplant. The probability of such cord blood ultimately being required for a person's own use is around 1 in 25.000.

- Public non-profit banks store CBUs for use by the international community - in other words, for unrelated persons (allogeneic donation). The typing markers are notified to the national central registers, which then anonymise and catalogue the tissue types of all voluntary donors with a donor identification number in a database. International networking enables fast and efficient location of suitable recipients. Inclusion in a donor register does not obligate a donor to actually donate at a later date. Financing comes from private donations, state funding, foundations and, indirectly, from health insurers. At present around 450.000 CBUs are publicly available worldwide.
- A combined form of bank offering both private and public services has recently been established on the market.

There are also banks that harvest and sell cord blood solely for medical research purposes.

Transplants

Successful transplantation of allogeneic stem cells depends on how well the tissue markers (HLA type) of the donor match those of the recipient so that the stem cells can be used after transplantation to build a new, functioning blood and immune system. Blood group is irrelevant to transplantation. At present, around 20% of patients take more than twelve months to find a suitable unrelated donor (for bone marrow, peripheral blood, or CBU).
Transplantation of stem cells takes place by intravenous infusion. Due to the low number of stem cells in the small volume of a CBU, adults often require two units for a successful transplantation. Cord blood banks store and administer the prepared transplant which can only be harvested once immediately after birth. If the donation meets the international standards for global use (American Association of Blood Banks, Foundation for the Accreditation of Cellular Therapy), it must be processed in a certified laboratory within 48 hours. The resultant transplant is then packaged in plastic bags, deep-frozen (cryopreservation) and stored in tanks of liquid nitrogen. Around 50% of donations do not meet the main criterion for storage - an adequate number of stem cells - and are discarded.

Operating a cord blood bank

There are international rules governing the operation of a cord blood bank: http://parentsguidecordblood.org/content/usa/banklists/regulations.shtml?navid=31
The quality criteria for registered cord blood banks operating in accordance with the standards are sufficiently defined by, for example, AABB accreditation, JACIE/NetCord-FACT accreditation, and by GMP, ISO 9001, ISO 17025, UK HTA and Swissmedic certification.

Costs

The costs of processing a stem cell transplant unit are around USD 45.000 for a unit from peripheral blood (PB), around USD 42.000 for a unit from bone marrow (BM) and around USD 22.000 for a cord blood unit (CBU). The costs of administration, registration and sourcing cost an additional USD 2.000 for PB units and USD 20.000 for BM units. As only around 5% of all CBUs worldwide have been used for transplantation to date, the costs of long-term transplant storage and administration are high, amounting to USD 320.000 or more per cord blood unit, plus the treatment costs of around USD 200.000 per patient (Journal of ClinicoEconomics and Outcomes Research, 2010:2 141-147).

Coverage of costs for storage and use is dependent on the individual health insurer concerned. As the medical costs of treatment are very high in most countries but are only partially covered by health insurers, many patients also choose to travel abroad for treatment.

Outlook

To date, cord blood stem cells are only donated from around 5% of all births in Germany, whereas in France and Spain the donation rate is higher at around 30%. As the advantages of rapid availability, lower infection risk and less likelihood of rejection of CBU transplants in comparison with BM and PB units become more generally known, it is probable that donation rates will rise sharply. More widespread advertising campaigns will also help to make a difference. It may be assumed that, due to competition and mergers, the prevailing business model for cord blood banks will be profit-oriented, offering a complete service (including laboratory operation and global transport logistics). Such banks will also sell donations for research purposes. International guidelines and new laws will increasingly regulate harvesting, operation, use and international resource-sharing.

Information for the underwriter

For insurers, all this means that there will be demand for covers offering very long-term operational guarantees (guaranteed continued storage and maintenance in the event of insolvency, protection against any kind of loss, transport cover, D&O, E&O, employee liability insurance, protection for data storage, undisrupted IT communications). Health insurers will increasingly be required to take a stance on coverage of costs. There will be rising demand for patient reimbursement programmes, health insurance products, alternative financing for harvesting, tissue typing, processing and storage and, in particular, treatment costs for possible future disorders that might require treatment, which are not currently borne by insurance companies. Cover concepts will also be required for the processing of cross-border health-related costs and the organisation of global courier transportation.

For CBUs to be immediately available requires complex interaction between an international network of cord blood banks and intercontinental transport logistics. At present, in 40% of cases the donor and the recipient are in different countries.

An increasing need for special liability coverage for doctors who harvest the cord blood, midwives, laboratory personnel and cord blood bank operators is additionally likely. There could also be strong demand for combination products (e.g. storage and treatment) from an insurance perspective.

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