Health Technology Review	
Technology Ref.:	HTA23070
Technology Name/Version/Model:	Human Amniotic Membrane Allograft; 1. BIOVANCE , 2. 3L BIOVANCE , 3. BIOVANCE 3L Ocular
Approvals by International Bodies:	FDA - SAUDI FDA
Company name:	Manufacture name: Celularity / origin; United State of America
Agent in UAE:	Abu Dhabi Ports Medical Store
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Short Description of the Technology:	The technology (Human Amniotic Membrane Allograft) is a decellularized, dehydrated amniotic membrane that is used to cover or wrap exposed tendon, ligament, soft tissue, full thickness wounds, and the ocular surface. It is a three-dimensional structure that attracts the adjacent cells to regenerate injured tissue at a rapid rate. It is placed on a full thickness wound after wound debridement or it can be placed on injured tissue in the operating room and sutured to the tissue. The product is placed similar to other grafts or scaffolds that have been used in the region. The benefit of this product is that because of the proprietary processing, all remnant proteins, cytokines, and residual cell debris are eliminated. This prevents an inflammatory response and faster regeneration of the tissue.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

Summary of Review: BIOVANCE, a Human Amniotic Membrane Allograft developed by Celularity, is a versatile biological membrane that promotes faster tissue regeneration and wound healing by providing a protective extracellular matrix. This technology can be used for various applications, including surgical coverings, wound treatments, and ocular injuries. It is easy to handle, requires no preparation, and has a 10-year shelf life at room temperature. The benefit of this product is that because of the proprietary processing, all remnant proteins, cytokines, and residual cell debris are eliminated. This prevents an inflammatory response and faster regeneration of the tissue.

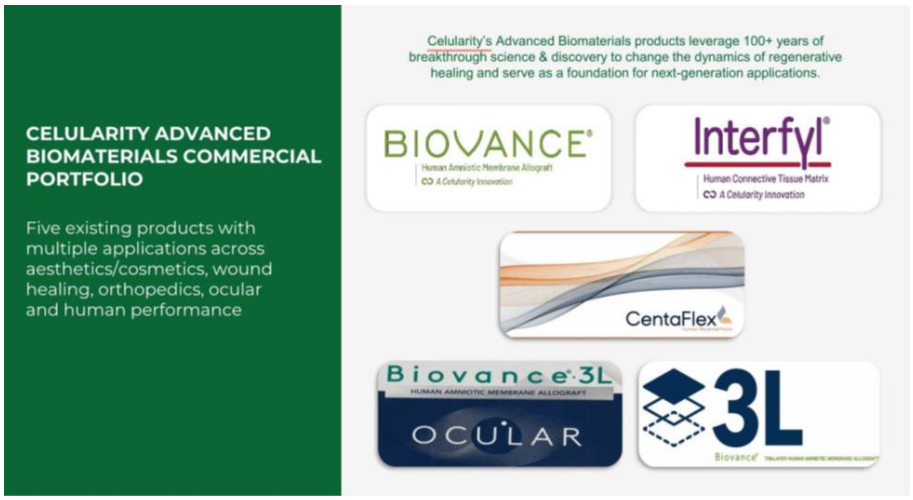
Advantages	Disadvantages
Provides a biological membrane that promotes faster tissue regeneration and wound healing by attracting adjacent cells.	Effectiveness depends on proper application and conditions such as non-infected tissue and good blood flow. Incorrect use could reduce efficacy.
Can be used for various types of wounds, including surgical coverings, wraps, barriers, partial- and full-thickness wounds, burns, ulcers, and ocular injuries.	Similar risks as other grafts and scaffolds, including contraindications in settings of infection, inadequate blood perfusion, and malignant neoplasm.
The proprietary processing eliminates remnant proteins, cytokines, and cell debris, reducing the risk of inflammation and promoting faster healing.	While it has a long shelf life at room temperature, once opened, the allograft must be used immediately or discarded, which could lead to potential waste if not used promptly
The product has a 10-year shelf life at room temperature, making it convenient for storage and reducing the need for special equipment.	
No preparation required (no thawing, rinsing, or soaking), flexible and easy to handle, can be applied with either side facing the tissue, and does not require specific orientation.	

We recommend an approval of using this technology for Market entry with the following conditions:

1. For proper clinical application use this technology only after thorough wound debridement for full-thickness wounds.
2. Select patients based on clinical need, prioritizing those with chronic non-healing wounds and do o not use in patients with active infections, or inadequate blood perfusion.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image



Population, setting and intended user for Technology "Human Amniotic Membrane Allograft"

- Population/ Intended User;
  - Suited for a variety of surgical and wound applications where there is a need to replace or supplement damaged or inadequate integumental tissue.
  - Ideal solution for tunneling and satellite wounds

- To be performed by:
  - By surgeons
- Clinical Setting:
  - Hospitals, special surgery centers
- Condition of use:
  - augmentation of deficient/inadequate soft tissue and treatment of deep dermal wounds; Tears.
  - surgical wounds; soft tissue voids as a result of tunneling wounds, fistula tracts.
  - dermal undermining including those with exposed vital structures (bone, tendon, ligament, or nerve).
  - Diagnosis with end stage joint arthritis.
  - exhausted all forms of conservative treatment.
  - elected to undergo foot and/or ankle arthrodesis.

- exclusion criteria:
  - use of post operative bone stimulator.
  - history of active target joint infection in 6 months prior to surgery.
  - malignant neoplasm.
  - inadequate blood perfusion