SimpliMax

Amniotic Membrane Allograft

Human amniotic membrane forms the innermost layer of placenta tissue. The avascular membrane acts as a protective barrier for the developing fetus. Its properties provide a wide variety of potential benefits in regenerative medicine.

SimpliMax Key Features & Properties:

- Placental tissue allograft composed of dual layer amnion
- Non-side specific orientation for application
- Thicker membrane for deep wounds or exposed anatomy that can be easily positioned or repositioned for improved conformity
- Enhanced tensile strength, adheres well, and easy to apply
- Can be used in a hydrated or dehydrated state

SimpliMax Ordering Information | Q4341

Product SKU	Product Size (Cm)
SMAX AA 0202	2x2
SMAX AA 0203	2x3
SMAX AA 0404	4x4
SMAX AA 0406	4x6
SMAX AA 0408	4x8
SMAX AA 1010	10x10
SMAX AA 2024	20x24

SimpliMax is a dehydrated, dual-layer amnion membrane allograft. The allograft is derived from human placental membrane collected from a consenting donor and processed aseptically. It is terminally sterilized to achieve a sterility assurance level (SAL) of 1 x 10-6 utilizing gamma irradiation. SimpliMax is packaged as a sterile product in sealed, single-use pouches. SimpliMax is processed in compliance with all current Good Tissue Practices as mandated by the United States Food and Drug Administration and the American Association of Tissue Banks.
Only tissues from donors meeting the prescribed criteria are processed for manufacturing of SimpliMax

Order & Customer Support Contact Details
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General Information

Reimbursement and coverage eligibility for the use of SimpliMax Amniotic Membrane Allograft and associated procedures varies by Medicare and private payers. Coverage policies, prior authorizations, contract terms, billing edits, and site-of-service influence reimbursement.

Place of Service (POS) Codes

POS codes are 2-digit numbers included on health care professional claims to indicate the setting in which a service was provided. The Centers for Medicare and Medicaid Services (CMS) maintain POS codes used throughout the healthcare industry. These codes should be used on professional claims to specify the entity where service(s) were rendered. Check with individual payers for reimbursement policies regarding these codes.

Place of Service Code	Place of Service Location	Place of Service Description
11	Office	Location other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or Local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
12	Home	Location, other than a hospital or other facility, where the patient receives care in a private residence.
32	Nursing Facility	A facility which primarily provides to residents skilled nursing care and related services for the rehabilitation of injured, disabled, or sick persons, or, on a regular basis, health-related care services above the level of custodial care to other than individuals with intellectual disabilities.

SimpliMax Amniotic Membrane Allograft (Q4341) is included on the Medicare Part B Average Sales Price (ASP) Drug Pricing File published quarterly by the Centers for Medicare and Medicaid Services (CMS).
Average Sales Price information is published quarterly by the Centers for Medicare and Medicaid Services (CMS) in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File. Providers are encouraged to review the ASP Pricing files posted quarterly by CMS and listed by HCPCS on CMS.gov for updates. Payment allowance limits that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing. In determining the payment limit based on WAC, the contractors follow the methodology specified in Publication. 100-04, Chapter 17, Drugs and Biologicals, for calculating the Average Wholesale Price (AWP), but substitute WAC for AWP. Providers are encouraged to check with their local MACs for information on established rates.
Providers are also encouraged to check with payers to determine if an invoice is required to be submitted with the claim and/or in Box 19 of the CMS-1500 claim form.

CPT® Coding

The Current Procedural Terminology (CPT) code set describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes. Physicians should report all surgical and medical services performed, and are responsible for determining which CPT® code(s) are appropriate.

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References: CMS Manual for that detail Section 20 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf

Procedure coding should be based upon medical necessity, procedures and supplies provided to the patient. Coding and reimbursement information is provided for educational purposes and does not assure coverage of the specific item or service in a given case. Replicate makes no guarantee of coverage or reimbursement of fees. These payment rates are nationally unadjusted average amounts and do not account for differences in payment due to geographic variation. Contact your local Medicare Administrative Contractor (MAC) or CMS for specific information as payment rates listed are subject to change. To the extent that you submit cost information to Medicare, Medicaid or any other reimbursement program to support claims for services or items, you are obligated to accurately report the actual price paid for such items, including any subsequent adjustments. CPT five-digit numeric codes, descriptions, and numeric modifiers only are Copyright AMA.