Medical Necessity Guideline

| Medical Necessity Guideline (MNG) Title: Dehydrated human amniotic membrane (Epifix) MNG |
|---------------------------------|-----------------|-----------------|
| MNG #:044 | ☒ SCO ☒ One Care | Prior Authorization Needed? ☒ Yes ☐ No |
| Clinical: ☒ | Operational: ☐ | Informational: ☐ |
| Medicare Benefit: ☒ Yes ☐ No | Approval Date: 8/5/2020 | Effective Date: 12/18/2020 |
| Last Revised Date: | Next Annual Review Date: 08/05/2021 | Retire Date: |

OVERVIEW:
Dehydrated human amniotic membrane (‘Epifix’) is a biologic wound dressing to cover, protect, and encourage healing of difficult-to-heal chronic venous or diabetic partial and full-thickness ulcers of the legs or feet that have failed standard wound therapy after at least 4-weeks of standard more conservative therapy.

This dehydrated human amniotic membrane (‘Epifix’) is cleaned, dried, sterilized, prepared and packaged from the covering of placentas. It is approved by the FDA and is MORE effective at less cost than Apligraf in healing chronic wounds of skin which lacks enough blood flow to heal normally as a result of blocked arteries from diabetes, tobacco abuse, and other peripheral vascular disease.

This skin covering may be applied weekly for up to five weeks of treatment. After such time it is recommended to resume routine wound care and look for other reversible causes of the wounds and risk factors in question.

DECISION GUIDELINES:
Clinical Coverage Criteria:
CCA will cover dehydrated human amniotic membrane (‘Epifix’) up to five weekly applications according to the following criteria:

- a. Member has a chronic skin wound from diabetes or vascular disease
- b. The wound has not decreased in surface area and depth in four weeks of conservative care
- c. Member has not already received 5 weekly applications of this covering to this wound

Note that for all above criteria that specify a specialty, the PCP may prescribe the agent AS LONG AS there is documentation of the active, regular involvement of the appropriate specialist, as documented by up to date office notes or equivalent.

Disclaimer:
This Medical Necessity Guideline is not a rigid rule. As with all of CCA’s criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the
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request), or describing the member’s unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member’s unique clinical circumstances will generally be required.

RELATED REFERENCES:

- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4232235/
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5220025/

ATTACHMENTS:

| EXHIBIT A: |
| EXHIBIT B |

REVISION LOG:

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