

This content has been created to supplement the MCG care guidelines. MCG Health has neither reviewed nor approved the modified material.

RMHP Bioengineered Skin Substitute and Wound Care Products

MCG Health
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[Link to Codes](#)

- [Clinical Indications for Procedure](#)
- [Description](#)
- [Reviewer Guidance](#)
- [References](#)
- [Policy History](#)
- [Codes](#)

Clinical Indications for Procedure

[Return to top of RMHP Bioengineered Skin Substitute and Wound Care Products - AC](#)

For **ALL health care plans**, RMHP follows the Centers for Medicare and Medicaid (CMS) services Local Coverage Determination (LCD) and Local Coverage Article (LCA). The case will be pended for the reviewer to apply the Coverage Indications, Limitations, and/or Medical Necessity, along with US Food and Drug Administration (FDA) regulations. The requesting provider will be notified of the decision per protocol. See Reviewer Guidance.

Description

[Return to top of RMHP Bioengineered Skin Substitute and Wound Care Products - AC](#)

RMHP follows the CMS LCD and LCA for all plan types. The text of this policy is derived from these documents. See References.

History/Background and/or General information - The addition of Skin Substitutes or Cellular or Tissue Based Products (CTPs) to certain wounds may afford a healing advantage over dressings and conservative treatments when these options appear insufficient to affect complete healing. There are currently a wide variety of bioengineered products available for soft tissue coverage to affect closure. These products may be derived from allogeneic, xenogeneic, synthetic sources or a combination of any or all of these types of materials. However, without the component of the recipient's own distinct epithelium and cellular skin elements, permanent skin replacement or coverage by the graft cannot be accomplished.

Reviewer Guidance

[Return to top of RMHP Bioengineered Skin Substitute and Wound Care Products - AC](#)

The reviewer will apply the LCD (including FDA) and LCA guidance including coverage indications and **LIMITATIONS** / FDA designation / on label use / status, and medical necessity. See References for full titles.

References

[Return to top of RMHP Bioengineered Skin Substitute and Wound Care Products - AC](#)

Local Coverage Determination (LCD): Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041) original effective date 10/01/2015, revision effective date 9/26/2019, **reviewed 7/20/2023** - document not updated since 9/26/2019.

Local Coverage Article (LCA): Billing and Coding: Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (A54117) original effective date 10/01/2015, revision effective date 8/13/2020, **reviewed 7/20/2023** - document not updated since 8/13/2020.

Updated designation and approved usage criteria may be found under Medical Devices/Products and Medical Procedures at: <http://www.fda.gov/>

Policy History

[Return to top of RMHP Bioengineered Skin Substitute and Wound Care Products - AC](#)

History Summary: 10/3/2019 RMHP adopted CMS LCD, LCA and FDA guidance. 6/9/2020 Annual review - updated references. 7/16/2020 Added new HCPCS codes effective 7/1/2020. Updated reference review date. 9/15/2021 annual review and update. 12/6/2021 Added new HCPC codes. 12/21/2021 Added HCPCS codes effective 1/1/2022. 4/20/2022 Annual review and updated to add new HCPCS codes effective 4/1/2022. 6/20/2022 Added new HCPCS codes eff 7/1/2022. 3/4/2023 Annual review with new HCPCS codes added. 7/20/2023 reviewed; added new HCPCS codes effective 7/1/2023.

Codes

[Return to top of RMHP Bioengineered Skin Substitute and Wound Care Products - AC](#)

HCPCS: A2001, A2002, A2003, A2004, A2005, A2006, A2007, A2008, A2009, A2010, A2011, A2012, A2013, A4100, C1849, Q4100, Q4101, Q4102, Q4103, Q4104, Q4105, Q4106, Q4107, Q4108, Q4110, Q4111, Q4113, Q4114, Q4115, Q4116, Q4117, Q4118, Q4121, Q4122, Q4123, Q4124, Q4125, Q4126, Q4127, Q4128, Q4130, Q4132, Q4133, Q4134, Q4135, Q4136, Q4137, Q4138, Q4139, Q4140, Q4141, Q4142, Q4143, Q4145, Q4146, Q4147, Q4148, Q4149, Q4150, Q4151, Q4152, Q4153, Q4154, Q4155, Q4156, Q4157, Q4158, Q4159, Q4160, Q4161, Q4162, Q4163, Q4164, Q4165, Q4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4173, Q4174, Q4175, Q4176, Q4177, Q4178, Q4179, Q4180, Q4181, Q4182, Q4183, Q4184, Q4185, Q4186, Q4187, Q4188, Q4189, Q4190, Q4191, Q4192, Q4193, Q4194, Q4195, Q4196, Q4197, Q4198, Q4199, Q4200, Q4201, Q4202, Q4203, Q4204, Q4205, Q4206, Q4208, Q4209, Q4210, Q4211, Q4212, Q4213, Q4214, Q4215, Q4216, Q4217, Q4218, Q4219, Q4220, Q4221, Q4222, Q4224, Q4225, Q4226, Q4227, Q4228, Q4229, Q4230, Q4231, Q4232, Q4233, Q4234, Q4235, Q4236, Q4237, Q4238, Q4239, Q4240, Q4241, Q4242, Q4244, Q4245, Q4246, Q4248, Q4251, Q4252, Q4253, Q4254, Q4255, Q4256, Q4257, Q4258, Q4259, Q4260, Q4261, Q4262, Q4263, Q4264, Q4272, Q4273, Q4274, Q4275, Q4276, Q4277, Q4278, Q4280, Q4281, Q4282, Q4283, Q4284

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