



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, OH

Appeal of: [REDACTED] WOUND CARE

OMHA Appeal No.: [REDACTED]

Beneficiary: [REDACTED]

Medicare Part: B

Medicare No.: [REDACTED]

Before: **Bill Wells**
Administrative Law Judge

DECISION

After considering the evidence and arguments presented in the record, I issue a **FULLY FAVORABLE** decision. Medicare covers the 15271: skin sub graft and O4205: membrane graft or wrap (wound cover) that was provided to the beneficiary on [REDACTED] (date of service). There was no overpayment

PROCEDURAL HISTORY

The provider submitted a claim for the wound cover at issue which was provided to the beneficiary on the date of service. The claim was paid initially, however it was later determined that an overpayment occurred. Upon redetermination by the Medicare Administrative Contractor (MAC), the overpayment was upheld. (File 15, pp. 5-10). At reconsideration, the Qualified Independent Contractor (QIC) issued an unfavorable decision, holding the provider liable for the overpayment. (File 22, pp. 1-10).

A request for an Administrative Law Judge (ALJ) Hearing was subsequently filed with the Office of Medicare Hearings and Appeals (OMHA), which satisfied all applicable jurisdictional requirements found in 42 C.F.R. §§ 405.1002 and 405.1006. (File 21, pp. 1-3).

A telephonic hearing was held on [REDACTED]. This is one of two cases addressing similar issues for the same appellant and beneficiary, both addressed in one hearing. Appearing on behalf of the appellant, [REDACTED] Wound Care, were **Lance McNeill**, Office Manager, and [REDACTED], PA, and part owner of the company. The MAC, Novitas, waived its right to hear and submitted a position paper in lieu of attendance at hearing. (File 43, pp. 1-47). All exhibits were entered into the record without objection and the administrative record is now closed.

ISSUE

Whether Medicare covers the wound cover provided to the beneficiary on the date of service at issue, and if not, who is responsible for the non-covered charges.

APPLICABLE LAW AND POLICY

Section 1832 of the Act entitles Medicare Part B beneficiaries to have payment made to them or on their behalf for medical and other health services. Act § 1832(a)(1). Medical and other health services are defined in section 1861(s) of the Act.

Section 1862(a)(1)(A) limits Medicare payments to items or services that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,” notwithstanding any other provision of Title XVIII of the Act. See also 42 C.F.R. § 411.15(k)(1). If a service or item is denied coverage based on § 1862(a)(1)(A) or certain other provisions of the Act, the limitations on liability provisions, set forth in § 1879 of the Act, may be applied to potentially limit a party’s liability for the costs of the non-covered claim. See also 42 C.F.R. §411.406 and 42 C.F.R. §411.404(b).

42 CFR § 424.5(a)(6) sets forth that the provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment.

CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Publ’n 100-8)* ch. 3, § 3.3.2.1, reads in relevant part that for Medicare to consider coverage and payment for any item or service, the information submitted by the supplier or provider must corroborate the documentation in the beneficiary’s medical documentation and confirm that Medicare coverage criteria have been met.

CMS, *Medicare Program Integrity Manual (MPIM)*, pub. 100-8, chapters 3 and 13, provide guidance for determining whether a product, service or item is medically reasonable and necessary for purposes of Medicare coverage in circumstances where there is no NCD, LCD, or other CMS policy available in the Medicare manuals. (See MPIM, ch. 3, § 3.6.2.2, and ch. 13, § 13.5.4).

CMS, *Medicare Benefit Policy Manual (MBPM)*, (Internet-Only Publ’n 100-2) ch. 15 ch. § 50 and ch. 16, § 20 provides the criteria for the coverage of biologics, also referred to as HCT/Ps, and provides that biologicals are covered if, among other criteria, the biologic has not been determined by the FDA to be less than effective. See also, CMS, *Medicare Claims Policy Manual (MCPM) (Internet-Only Publ’n 100-4)* ch. 12, §§ 30 and 40.

FINDINGS OF FACT AND ANALYSIS

At issue in this case is whether the use of the wound cover provided to the beneficiary on the date of service is covered by Medicare. More specifically, the inquiry is whether the wound cover is considered experimental or investigational.

At the most recent level of appeal, the QIC found:

A reconsideration request was submitted to appeal the denial of the above service. The QIC has reviewed the case file and evidence submitted by the appellant. In review of the documentation provided, the beneficiary was evaluated for advanced wound therapy for a non-healing pressure ulcer. The medical records contain a letter as well as a visit note to support the procedure was performed

along with the baseline assessment and trialed conservative treatment. The documentation supports measurements as well as amount of product used and wasted. The QIC finds that Q4205 is experimental and investigational as denoted by the Q code status nomenclature. Under Medicare law, no payment can be made under Medicare for any expenses incurred for items or services that are considered investigational and are not considered reasonable and necessary. Although the UPIC cited LCD L35041 for application for bioengineered skin substitutes to lower extremity chronic non-healing wounds and the provider has argued LCD L35041 with the same title, the QIC has determined the correct policy is the Centers for Medicare and Medicaid Services, Internet Only Manual 100-08 — Medicare Program Integrity Manual (MPIM), Chapter 3, Section 3.6.2.2 and Section 1862 of the Act. Since Q4205 is considered investigational and is not payable as per CMS, it is the QIC's determination that the Q4205 does not meet the medically reasonable and necessary requirements of Section 1862(a)(1)(A) of the Act.

(File 22, p. 6).

The beneficiary in this case is a [REDACTED] who had a 4.8 cm abdominal aortic aneurysm and was initially evaluated for wound care in her home on [REDACTED]. (File 39, pp. 2-6). She previously had surgery on a chronically occluded superior mesenteric artery with previously placed celiac artery stent. *Id.* The beneficiary also has a past medical history significant for rheumatoid arthritis, hypertension, coronary artery disease with placement of a coronary artery bypass graft in [REDACTED], obesity, former smoker quit in [REDACTED], and pre-diabetes. *Id.*

The beneficiary presented to the hospital emergency room at the end of [REDACTED] with worsening nausea, dehydration, abdominal pain and leukocytosis. (File 39, pp. 2-6). She was found to have acute on chronic mesenteric ischemia. On [REDACTED] she underwent a supraceliac aorta to hepatic artery bypass procedure. *Id.* The beneficiary was discharged on antibiotics, and noticed purulent drainage to her surgical incision on [REDACTED]. *Id.* She was prescribed another 7 days of Cephalexin, and Santyl to help chemically debride the wound bed. *Id.* Previous wound care included soap and water cleansing in the shower, an abdominal pad over incision, and abdominal binder to secure dressing in place. *Id.* The wound/surgical incision measured 19.6x 3.8x0.5 cm on [REDACTED] by [REDACTED] Home health. *Id.*

The MAC's denial in his case was based on an assertion that the Biolab Sciences Inc.'s Membrane Wrap at issue was being used as a skin substitute graft or scaffolding for skin growth CPT code 15271 and not as a wound covering. (File 15, pp. 5-10). The reason this distinction between skin substitute graft and wound covering matters is that when used as a protective covering or barrier the product is regulated under Section 361 of the Public Health Service Act (PHSA), but if it is being used as a skin substitute to promote wound healing it would be regulated under Section 351 of the PHSA. The Membrane Wrap product is approved only under Section 361. If it is being used for a purpose that requires registration under Section 351, and if that registration is lacking (which it is in this case), then Medicare could not approve the use.

There is a letter dated Jan. 17, 2023, from the Food and Drug Administration (FDA) regarding the status of the Membrane Wrap product at issue here. Appellant cites this letter as proof that the product is approved and regulated under Section 361. (Hearing Recording). However, the MAC argues that the FDA correspondence is meaningless because it is based on information furnished by Biolab Sciences that the MAC contends is misleading. (File 43, pp. 5-14).

The MAC also argues that even if the Part 361 Approval is all that is required, there is insufficient published peer reviewed medical literature supporting that the product at issue is safe and effective (File 43, p. 13). On the other hand, appellant argues that, as a Section 361 “homologous use” product, the question of support in the medical literature for the product being safe and effective should be evaluated on a class-wide basis, and not on individual products. (Hearing Recording). On this issue, I find the appellant’s position on this point to be more persuasive and adopt it here.

Appellant acknowledged that the use of skin substitutes has greatly increased in recent years, and that this increased cost to Medicare has brought a great deal of additional scrutiny to cases involving the use of these products. (Hearing Recording). See also the CMS Press release of October 31, 2025, “CMS Modernizes Payment Accuracy and Significantly Cuts Spending Waste”¹ where it is reported that Medicare spending on wound care products known as skin substitutes has had unprecedented growth, rising from \$256 million in 2019 to over \$10 billion in 2024, according to Medicare Part B claims data. This dramatic spending increase is largely attributed to abusive pricing practices in the sector, including the use of products with limited evidence of clinical value.

Here the MAC claims that there is no documentation to support why the conservative treatments failed the beneficiary. (File 43, p. 13). However, the MAC cites no authority in support of the assertion that evidence as to why the conservative treatment failed is required. The record does contain good documentation regarding the conservative treatments which were attempted and failed to achieve satisfactory results. (File 5, pp. 1-4; File 39, pp. 2-240; Hearing Recording). These treatments included hospitalization for IV antibiotics and a negative pressure device. *Id.* The certificate of medical necessity from the beneficiary’s treating physician also addresses the need for the more advanced wound treatment technologies. *Id.* I find that the record and testimony in this case demonstrates that the provider tried many techniques, including multiple debridement procedures and the use of negative pressure devices before moving on to the use of skin substitutes in an attempt to promote wound healing.

Additionally, the appellant states that the MAC is asserting that any product with a “Q Code” is automatically experimental and investigational, and that certainly appears to be the case when reviewing the MAC’s position paper. (File 43, p. 6). I agree with and accept the appellant’s contention that the existence of a “Q Code” does not mean that the item to which it is attached is necessarily experimental or investigatory. (Hearing Recording). Q codes are merely temporary codes assigned by CMS to new or emerging medical procedures, services, and supplies that do not yet have an existing permanent code. They are used to facilitate billing and payment for new or emerging services.

The MAC also claims that Local Coverage Determination (LCD) L35041, “Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds” is not applicable to the claim in question because this claim did not involve diabetic foot ulcers or venous leg ulcers. (File 43, p. 6). The MAC is correct in this assertion, and the record shows that the wound at issue is a surgical wound of the abdomen. The appellant acknowledges this, but argues the LCD is still relevant to demonstrate the state of practice for the use of Bioengineered Skin Substitutes such as the one used here. (Hearing Recording). I find that the appellant is also correct in that assertion.

¹ <https://www.cms.gov/newsroom/press-releases/cms-modernizes-payment-accuracy-significantly-cuts-spending-waste> , last accessed November 14, 2025.

The MAC's position paper also discusses three different wounds which the beneficiary had. (File 43, pp. 5-14). However, since no skin substitutes were used in the treatment of the two smaller wounds, I find that the treatment of those wounds is not relevant to the question at issue, and they will not be considered further.

The only wound at issue is from when the beneficiary underwent bypass surgery on [REDACTED] during which the initial abdominal surgical incision was created. The record shows that, subsequently, the beneficiary experienced post-surgical wound dehiscence, resulting in an open abdominal wound. Dehiscence is a partial or total separation of previously approximated wound edges, due to a failure of proper wound healing. This scenario typically occurs 5 to 8 days following surgery when healing is still in the early stages. The causes of dehiscence are similar to the causes of poor wound healing and include ischemia, infection, increased abdominal pressure, diabetes, malnutrition, smoking, and obesity.² This is a common complication following vascular surgery, particularly in patients with comorbid conditions like this beneficiary. The record shows that the beneficiary had a history of smoking, pre-diabetes, and obesity.

The Q4205 (Amniotic Membrane "Membrane Wrap") — Real-World Case Series & Evidence Summary Supporting Reasonable and Medically Necessary Use report shows that the appellant, [REDACTED] Wound Care, provides quality care and has achieved excellent results for the nine patients followed, one of whom is the beneficiary in the case before me. While the inferences to be drawn from the study are weakened by the lack of testimony showing how the patients in the study were similar to the patient in question, it, clearly shows, among other things that the appellant is using data driven techniques to determine when the use of skin substitutes is likely to be helpful, and to track the progress of the patient so that if what they are doing is not working, they can try something else. It is also of importance to note that according to the testimony [REDACTED] Wound Care sparingly uses skin substitute products, and uses it in less than [REDACTED] of their cases. (Hearing Recording).

The key remaining issue to be examined is whether the use of the Q4205 is a homologous or non-homologous use? If it is a non-homologous use, it would have to be approved under Section 351 of the PHSA. While it is an admittedly a close case, I accept the appellant's contention that for this patient the Q4205 was being used as a protective wound covering, which is a recognized homologous use and therefore is covered under Section 361.

Based on the foregoing considerations, I find that the record demonstrates by a preponderance of the evidence that the wound cover provided to the beneficiary on the date of service at issue was used as a wound covering, was not investigational or experimental, was FDA approved, and was medically reasonable and necessary for this beneficiary. Accordingly, I find that Medicare Part B covers the claim and liability is no longer at issue.

CONCLUSIONS OF LAW

I conclude that the 15271: skin sub graft and Q4205: membrane graft or wrap provided to the beneficiary on the date of service at issue were medically reasonable and necessary. Accordingly, I find that the provider is entitled to reimbursement under Title XVIII of the Act.

² See the National Library of Medicine definition (<https://www.ncbi.nlm.nih.gov/books/NBK551712/#:~:text=Dehiscence%20is%20a%20partial%20or%20total%20separation,causes%20of%20poor%20wound%20healing%20and%20include>), last accessed November 14, 2025.

ORDER

For the reasons discussed above, this decision is **FULLY FAVORABLE**. I direct the Medicare Administrative Contractor to process the claim in accordance with this decision.

SO ORDERED

A handwritten signature in black ink, appearing to read "Bill C. Wells", written in a cursive style.

Bill Wells
Administrative Law Judge