Collagen Wound Dressings and Fillers

MEDICAL POLICY NUMBER: 457

Effective Date: 9/1/2026

Last Review Date: 6/2026

Next Annual Review: 6/2027

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Notes:

- Surgical dressings are described as passive wound coverings used to protect, absorb, or maintain a moist wound environment, while skin and tissue substitute products are biologically or structurally active products intended to promote tissue regeneration when a wound fails to heal with standard care. This medical policy is specific to collagen dressings and fillers only. It does **not** apply to skin/tissue substitute products or cellular and/or tissue-based products or CTPs. For skin substitutes/CTPs, reference the separate medical policy (see Cross References).
- In addition, this policy is specific to wound dressings used in a **home** setting for in-home dressing changes. It does **not** apply to in-facility or office use of wound dressings.

Covered Indications

I. A one-month supply of collagen wound dressings (A6021-A6023) or collagen wound fillers (A6010, A6011, and A6024) for the treatment of wounds may be considered **medically necessary** when **all** of the following (A.-C.) criteria are met

A. The wound meets **all** of the following criteria (1.-3.):
   1. The wound must be an open wound (see Policy Guidelines for a definition); and
   2. The wound meets **one** of the following (a **or** b):
      a. Wounds caused or treated by a surgical procedure when the wound is closed by secondary or tertiary intention (see Policy Guidelines for a definition); **or**
      b. Wounds following debridement (by any debridement technique; e.g., surgical, mechanical, chemical, autolytic); **and**

3. The wound meets **one** of the following requirements (a.-n.):
    a. Partial- or full-thickness wounds; **or**
    b. Pressure injuries (stage II-IV); **or**
    c. Venous ulcers; **or**
    d. Ulcers caused by mixed vascular etiologies; **or**
    e. Diabetic ulcers; **or**
    f. First- and second-degree burns; **or**
    g. Donor sites and other bleeding surface wounds; **or**
    h. Abrasions; **or**
    i. Trauma wounds healing by secondary intention; **or**
    j. Dehisced wounds; **or**
    k. Surgical wounds; **or**
    l. Dehisced surgical wounds; **or**
    m. A wound with light to moderate exudate; **or**
    n. A wound that has stalled or has not progressed toward a healing goal.

B. The collagen product meets **all** of the following coverage criteria (1.-4.):
1. The dressing will be used as a **primary** dressing (a therapeutic or protective covering applied directly to wounds or lesions; ***and***
2. For HCPCS codes A6021-A6023, the product must have completed a Medicare coding verification review (CVR) **and** has been assigned to the HCPCS code submitted, as published on the PDAC Product Classification List (PCL) website; ***and***
3. For HCPCS code A6024, the product must be listed on the PDAC Product Classification List (PCL) website as a product assigned to the HCPCS code used; **and**
4. The wound dressing or filler must have been tailored to the specific needs of the individual patient. For wound dressings, the dressing size is based on and appropriate to the size of the wound (for wound covers, the pad size is usually about 2 inches greater than the dimensions of the wound).

C. **All** of the following (1-3) are met:
1. The collagen wound dressing or filler has been ordered by a healthcare provider who is actively treating and monitoring the wound healing progress (according to the LCD and LCA, a new order is required at least every 3 months); ***and***
2. The medical records document regular evaluations of the wound(s) by the treating provider (or their designee) on **no less than a monthly basis**, documenting healing progress. (**NOTE:** According to the LCD and LCA, regular wound evaluations are expected on at least a monthly basis, with heavily draining or infected wounds or members in a skilled nursing facility requiring weekly evaluations. This evaluation is required unless there is documentation in the medical record which justifies why an evaluation could not be done within this timeframe and what other monitoring methods were used to evaluate the patient's need for ongoing use of dressings.)
3. The medical plan includes weekly follow-up with the Wound Care Provider (MD, DO, APP).

Non-Covered Indications

II. A collagen based wound dressing or filler is considered **not medically necessary** when the above criterion I is not met, including but not limited to:

A. Any of the following wound types/characteristics (1.-7.):
   1. Closed wounds (including acute post-operative wounds); **or**
   2. Third-degree burns (other types of dressings are available for use for third-degree burns); **or**
   3. When an active vasculitis is present; **or**
   4. Drainage from a cutaneous fistula, including chronic or non-healing fistulas (e.g., enterocutaneous fistulas related to bowel injury, intra-abdominal surgery, trauma, diverticulitis, inflammatory bowel disease, or radiation), particularly when not actively draining gastric contents and demonstrating failure to progress in healing; **or**
   5. Stage 1 pressure ulcer; **or**
   6. A venipuncture or arterial puncture site (e.g., blood sample); **or**
   7. Wounds caused by trauma that do not require surgical closure or debridement, including partial- or full-thickness traumatic wounds that demonstrate failure to progress in healing (e.g., stalled in the inflammatory phase).

B. Dressings that have **not** been ordered by a treating practitioner, or documentation does not support regular evaluations of the wound and healing progress (this includes any direct-to-consumer products without a physician order and regular wound evaluations); **or**

C. Products billed using HCPCS code A6021-A6024, but the product is **not** on the PCL for that particular HCPCS code, the claim line may be denied as **incorrect coding.** Examples of codes not found on the PCL include HealPACK (by Encore, product number ECD-030); ***or***

D. Wound dressings or fillers **not** tailored to the needs of the individual patient, ***or***

E. Use of dressings on *intact* skin*; **or***

F. Collagen wound dressings and fillers used as a ***secondary*** wound covering and not in direct contact with the wound; ***or***

G. Quantities which exceed more than a one-month supply.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Skin and Tissue Substitutes, MP16

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

This policy may be primarily based on the following Center for Medicare and Medicaid Services (CMS) guidance resources:

- Local Coverage Determination (LCD): Surgical Dressings (L33831)[1]
- Local Coverage Article (LCA): Surgical Dressings – Policy Article (A54563)[2]

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- All medical records and chart notes pertinent to the request. This includes:
  - History
  - Physical examination
  - Treatment plan

DEFINITIONS

Open Wound: An open wound is an injury involving an external or internal break in body tissue, usually involving the skin.

Wound Intention:

- *Primary Intention:* Wounds are closed immediately after injury or surgery by directly approximating the wound edges, typically using sutures, staples, adhesive strips, or tissue glue.
- *Secondary Intention:* Wounds are left open and heal naturally through granulation tissue formation, contraction, and epithelialization rather than being sutured closed.
- *Tertiary Intention:* Wounds are initially left open to allow for drainage, reduction of contamination, or infection control, and are closed surgically at a later time once the wound is clean.

BACKGROUND

Collagen Wound Dressings
Collagen coverings applied to wounds or lesions either on the skin or caused by an opening to the skin.

Collagen Fillers
Primary dressings made of collagen placed into open wounds to eliminate dead space, absorb exudate, or maintain a moist wound surface.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of collagen wound dressings and fillers as a treatment for wounds. Below is a summary of the available evidence identified through May of 2026.

General Wound Care

- In 2022, ECRI conducted a Clinical Evidence Assessment evaluating the use of CellerateRX activated collagen as an adjunct to standard wound care for promoting wound healing.[3] A structured literature search identified two randomized controlled trials (RCTs) comparing CellerateRX plus usual care with conventional dressings alone or with other adjunctive treatments (e.g., platelet-rich plasma) across surgical populations, including total joint arthroplasty and radical mastectomy. Outcomes assessed included wound size, drainage, blood loss, postoperative complications, and adverse events.

  Across the two small RCTs (total n≈170), CellerateRX demonstrated some favorable effects, including reductions in blood loss, wound drainage, and certain complication rates compared with conventional care; however, results were inconsistent and not reproducible across studies due to heterogeneous patient populations, procedures, and outcome measures. Additionally, the evidence base was limited by small sample sizes, lack of blinding, short follow-up durations, and absence of key patient-centered outcomes such as time to complete healing or quality of life. The authors concluded that current evidence is insufficient to establish clinical effectiveness, and larger, well-designed multicenter trials are needed before routine use can be supported.

Pressure Injuries

- In 2019, Furuya-Kanamori et al. conducted a systematic review and network meta-analysis to compare the effectiveness of topical treatments for the healing of pressure injuries.[4] Randomized controlled trials were systematically identified across multiple databases, with independent reviewers extracting data and assessing risk of bias. The primary outcome was complete wound healing, and treatments were grouped into five categories based on mechanism of action, including active wound dressings, which encompassed collagen-based products.

  Forty trials involving 1,757 participants were included. All advanced dressing groups demonstrated higher point estimates for healing compared with basic dressings. Active wound dressings (including collagen) ranked more favorably than basic and hydroactive dressings; however, treatment effect estimates were imprecise, and only foam dressings showed statistically significant superiority. The authors concluded that basic dressings should be discontinued in favor of advanced options, with hydroactive dressings remaining standard practice. While collagen dressings may be used in appropriately selected wounds, the evidence was insufficient to support their routine preferential

use, and further high-quality studies are needed to clarify their optimal role and timing in pressure-injury management.

Non-Healing Wounds

- In 2017, Wu et al. conducted a narrative literature review and multidisciplinary expert panel assessment to evaluate the clinical utility of oxidized regenerated cellulose (ORC)/collagen dressings in wound care.[5] A structured literature search across multiple databases identified peer-reviewed studies published between January 2000 and March 2016, and evidence was classified using established levels-of-evidence criteria. In parallel, a panel of 15 wound-care experts reviewed the literature and contributed clinical experience–based recommendations for appropriate use.

  Fifty-eight studies were included, with the majority representing lower levels of evidence (over half classified as expert opinion or case-based data). Among randomized controlled trials and observational studies, ORC/collagen dressings demonstrated biologic effects such as reduced protease activity and improved wound microenvironment, as well as clinical trends toward greater wound area reduction, increased healing rates, and shorter time to healing compared with standard dressings. However, findings were inconsistent, with several trials showing similar outcomes between ORC/collagen and comparator dressings, and some evidence favoring alternative advanced dressings in specific settings.

  The authors concluded that ORC/collagen dressings may be a useful adjunct in the management of chronic and complex wounds, particularly where inflammation, elevated protease activity, or stalled healing is present. However, the overall evidence base is limited by heterogeneity and a predominance of lower-quality studies. As a result, while these dressings can be considered in selected clinical scenarios, current evidence is insufficient to support their routine preferential use over other advanced dressings, and further high-quality comparative and economic studies are needed to better define their optimal role.

CLINICAL PRACTICE GUIDELINES

No clinical practice guidelines recommend collagen wound dressings or fillers as superior over other dressings and fillers.[6-9]

EVIDENCE SUMMARY

A review of the available literature suggests that evidence supporting the use of collagen-based wound dressings and fillers for wound management remains limited and of low certainty. Small randomized controlled trials evaluating activated collagen products such as CellerateRX have demonstrated modest improvements in surrogate outcomes, including reduced blood loss, drainage, and complication rates compared with standard care; however, findings are inconsistent across heterogeneous surgical populations and are limited by methodological shortcomings, including small sample sizes, lack of blinding, and short follow-up. Similarly, in pressure injury populations, systematic review and network meta-analysis data indicate that while advanced dressings (including collagen-based products) may be associated with improved healing compared with basic dressings, the effect estimates are imprecise and do not demonstrate clear superiority over other advanced modalities. Evidence in chronic and non-healing wounds, including studies of ORC/collagen dressings, shows biologically plausible benefits and trends toward improved healing outcomes, but results are variable and largely derived from lower-

quality or observational studies. Overall, current evidence is insufficient to establish clinical effectiveness or to support routine preferential use of collagen-based dressings or fillers over other wound care options, and no clinical practice guidelines recommend their use as superior, highlighting the need for additional high-quality comparative research.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

CODES*		
CPT	None	
HCPCS	A6010	Collagen based wound filler, dry form, sterile, per gram of collagen
	A6011	Collagen based wound filler, gel/paste, per gram of collagen
	A6021	Collagen dressing, sterile, size 16 sq. in. or less, each
	A6022	Collagen dressing, sterile, size more than 16 sq. in. but less than or equal to 48 sq. in., each
	A6023	Collagen dressing, sterile, size more than 48 sq. in., each
	A6024	Collagen dressing wound filler, sterile, per 6 inches

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted

code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.

- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
9/2026	New policy.