

PROVIDER ALERT



To: AmeriHealth Caritas Louisiana Providers

Date: August 20, 2026

Subject: Approved Clinical Policies

Summary: Six Approved Clinical Policies

AmeriHealth Caritas Louisiana would like to inform you of the clinical policy approved by the Louisiana Department of Health in accordance with La. R.S. 46:460.54. The guideline is effective **September 20, 2026**, and will be located at the following link on our website under Clinical Policies:

<https://www.amerihealthcaritasla.com/provider/resources/clinical-policies>

1. [Autologous Fat Grafting and Injectable Soft-Tissue Fillers](#)
2. [Balloon Spacer Devices for Management of Massive Rotator Cuff Tears](#)
3. [Pediatric bed enclosures](#)
4. [Skin Substitutes for Chronic Wounds](#)
5. [Transcatheter Therapy for Severe Tricuspid Insufficiency](#)
6. [ZOLL Heart Failure Management System](#)

Questions: Thank you for your continued support and commitment to the care of our members. If you have questions about this communication, please get in touch with AmeriHealth Caritas Louisiana Provider Services at 1-888-922-0007 or your [Provider Network Management Account Executive](#).

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Autologous Fat Grafting and Injectable Soft Tissue Fillers

Clinical Policy ID: **CCP.1550**

Recent review date: **9/30/2025**

Next review date: **1/31/2027**

Policy contains: **autologous fat grafting, injectable fillers, breast reconstruction, systemic sclerosis, digital ulcers, chronic wounds, scar fibrosis, burn scars, fistula management, injection laryngoplasty, vocal fold paralysis, hyaluronic acid, poly-L-lactic acid, calcium hydroxylapatite, collagen, HIV-associated lipoatrophy**

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

Autologous fat grafting and injectable soft-tissue fillers (e.g., collagen, Sculptra, Radiesse) are clinically proven and, therefore, may be medically necessary for the following indications:

Autologous fat grafting:

- **Correcting contour irregularities and improving tissue quality after radiotherapy in postmastectomy breast reconstruction (Zhong, 2025)**
- **Adjunctively treating systemic sclerosis digital ulcers to promote healing when combined with systemic therapy (Campochiaro, 2025; Suliman, 2023)**

Injectable soft-tissue fillers:

- **Restoring facial volume in human immunodeficiency virus-associated facial lipoatrophy with agents recognized by the Food and Drug Administration (e.g., poly-L-lactic acid, calcium hydroxylapatite), improving volume and quality-of-life outcomes (Jagdeo, 2015)**

Additional uses for autologous fat grafting and injectable soft-tissues for vocal cord paralysis or glottic insufficiency are outlined in CCP.1157 Supraglottoplasty and laryngoplasty. All other uses of autologous fat grafting and injectable soft-tissue are considered investigational/not clinically proven and, therefore, not medically necessary. These include, but are not limited to:

- Using autologous fat grafting for generalized chronic wound management outside of systemic sclerosis digital ulcers; current evidence for generalized wounds is heterogeneous and characterized by very low certainty (Malik, 2020).
- Using injectable soft-tissue fillers for acne scar management, as the supporting evidence is characterized by heterogeneity and low quality (Albargawi, 2025).
- Using autologous fat grafting or injectable soft-tissue fillers for general aesthetic enhancement or to alter normal anatomic variation related to aging (cosmetic use).

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Implant or flap revision
- Capsulotomy/capsulectomy
- Local wound care
- Digital sympathectomy
- Revascularization procedures

Background

Autologous fat grafting is a surgical procedure involving the transplantation of an individual's own adipose tissue from one anatomical site to another for reconstructive or therapeutic purposes. The procedure involves harvesting adipose tissue via liposuction, processing the lipoaspirate using minimally manipulative techniques (e.g., centrifugation, filtration), and injecting the processed fat into the target area (Haddad, 2021). The mechanisms of action involve both structural replacement, restoring bulk in areas of volume loss (Lakhani, 2012) and regenerative effects, including the modulation of inflammation, promotion of angiogenesis, and remodeling of scar matrix (Schipper, 2024; Arena, 2025; Xiao, 2024). This policy addresses minimally manipulated autologous fat grafting, excluding enriched products such as stromal vascular fraction or nanofat.

Injectable soft tissue fillers are substances injected into the dermal or subcutaneous tissue. Common materials include hyaluronic acid, calcium hydroxylapatite, poly-L-lactic acid, and collagen. These agents serve as either physical fillers, providing immediate volume restoration (e.g., hyaluronic acid), or bio-stimulatory fillers, which stimulate natural collagen production (neocollagenesis) over time (e.g., poly-L-lactic acid, calcium hydroxylapatite) (Albargawi, 2025; Jagdeo, 2015).

While widely utilized for cosmetic enhancement (Amiri, 2024), both autologous fat grafting and injectable fillers are applied across diverse noncosmetic therapeutic and reconstructive indications. In reconstructive contexts, autologous fat grafting is used in post-mastectomy breast reconstruction to

manage contour irregularities and address tissue damage from radiotherapy (Zhong, 2025). Fillers such as poly-L-lactic acid and calcium hydroxylapatite are employed to treat human immunodeficiency virus-associated facial lipoatrophy, restoring facial volume loss related to antiretroviral therapy to reduce social stigma and improve quality of life (Jagdeo, 2015). Furthermore, autologous fat grafting has applications in tissue regeneration for the management of systemic sclerosis digital ulcers, chronic wounds, and burn scars (Campochiaro, 2025; Xiao, 2024; Lesmanawati, 2024).

Findings

Across noncosmetic indications, findings diverge by modality. Autologous fat transfer is endorsed for breast reconstruction and appears oncologically safe; in systemic sclerosis it improves short-term digital-ulcer healing, while effects on hand function and facial fibrosis are inconsistent and of lower certainty. Evidence for chronic wounds, scar fibrosis, and fistula care is low to very low, because studies are small and heterogeneous, and variable resorption limits durability. Injectable soft-tissue restore facial volume in human immunodeficiency virus-associated lipoatrophy, with hyaluronic acid safer but shorter-lived, poly-L-lactic acid longer-lasting but with more nodules, and calcium hydroxylapatite intermediate. Randomized trials remain scarce and technique variability limits generalizability, so conclusions distinguish guideline-supported practice from areas that remain investigational.

Guidelines

Autologous fat grafting in breast reconstruction

Society guidelines endorse autologous fat grafting as a reconstructive adjunct after oncologic breast surgery for contour correction, implant rippling, and irradiated skin improvement (Zhong 2025; American Society of Plastic Surgeons 2015). Ontario Health recommends fat grafting for these indications, citing improved patient-reported outcomes and no increased cancer recurrence based on a systematic review utilizing rigorous methodology, including the Appraisal of Guidelines for Research & Evaluation II framework (Zhong 2025). The American Society of Plastic Surgeons assigns a grade B recommendation based on consistent case-series evidence. They characterize the procedure as reconstructive, note its use for postmastectomy pain, and link coverage to the Women's Health and Cancer Rights Act while acknowledging insurer denials (American Society of Plastic Surgeons 2015).

Autologous fat grafting for systemic sclerosis

For digital ulcers in systemic sclerosis, the World Scleroderma Foundation conditionally advises autologous adipose tissue grafting as an adjunct to systemic therapy. This recommendation (evidence level three, expert opinion) is based on one randomized, controlled trial and cohort studies showing improved healing. The methodology included systematic reviews, Cochrane reviews, and the ROBINS-I (risk of bias in non-randomized studies of interventions) tool, and consensus procedures (Campochiaro 2025). The committee noted that other injectables, such as botulinum toxin for refractory ulcers, are supported mainly by observational data, highlighting evidence quality gaps that limit the strength of recommendations for those alternatives (Campochiaro 2025).

Systematic reviews and meta-analyses for autologous fat grafting

Breast reconstruction and oncologic safety

A large meta-analysis of 22 cohort studies (n = 9,971) provides moderate-certainty evidence regarding the oncologic safety of autologous fat grafting in individuals undergoing breast reconstruction after cancer treatment. The analysis found no increase in local recurrence, regional recurrence, distant metastasis, or mortality associated with fat grafting compared with controls (Tian, 2022). These findings establish the safety of the procedure in this specific oncologic population, supporting its use for reconstructive indications (Tian, 2022).

Systemic sclerosis

Autologous fat grafting is effective for digital ulcer healing in systemic sclerosis, although evidence is less robust for improving hand function or facial fibrosis. Multiple systematic reviews, 13 studies (n = 170) and 29 studies (n = 704), synthesizing data from prospective cohorts and one randomized, shamcontrolled trial reported high healing proportions and superiority of grafting over sham injection at eight weeks, supporting moderate certainty for short-term healing (Suliman, 2023); (Perrier, 2025). Regarding hand function and ischemic symptoms, reviews, 29 studies (n = 704), reported signals of reduced ischemic hand pain, but effects on mobility, grip measures, or range of motion were inconsistent, resulting in low certainty (Perrier, 2025). For facial fibrosis, improvements in mouth opening, mouth handicap scores, and subjective skin pliability were reported, but objective fibrosis measures were inconsistent, and the durability of effects remains uncertain due to variable graft resorption (Schipper, 2024).

Chronic wounds

The evidence regarding autologous fat grafting for generalized chronic wounds is characterized by significant heterogeneity and very low certainty, which is insufficient to establish the procedure as the standard of care. One systematic review of 10 observational studies (n = 389) analyzed various fat therapy techniques, attributing the very low certainty of evidence to the lack of controls, inconsistent reporting, and substantial procedural variations, despite noting a favorable safety profile (Malik, 2020). A separate meta-analysis of 21 randomized controlled trials (n = 1,119) suggested that human fat products, including minimally manipulated autologous fat grafting, accelerated wound healing rates, shortened time to complete healing, and reduced pain compared to conventional treatment (Xiao, 2024). However, the applicability of these findings to generalized chronic wound care remains limited by the very low certainty and heterogeneity noted across the broader literature.

Vocal fold insufficiency

Evidence regarding the efficacy of autologous fat grafting for vocal fold insufficiency is of very low certainty, primarily due to unpredictable graft durability and resorption. A Cochrane systematic review determined that no methodologically sound randomized controlled trials were available to compare the efficacy of autologous fat with other injectable materials for unilateral vocal fold paralysis (Lakhani, 2012). While systematic reviews of observational studies, 13 studies (n = 472), suggest short- to mediumterm improvements, these studies are subject to significant bias, lack control groups, and frequently show a decline in effect requiring reintervention (Campagnolo, 2023). A meta-analysis of 49 observational studies (n = 1,166) found statistically significant short-term improvements in the Voice Handicap Index, clinician-rated perceptual voice analyses, maximum phonation time, and acoustic parameters at six months (Haddad, 2021). The analysis found no significant difference in outcomes based on the use of liposuction or incision as the harvest technique (Haddad, 2021).

Scar fibrosis and burns

Systematic reviews examining autologous fat grafting for scar fibrosis suggest potential improvements in appearance but limited functional benefits, resulting in low certainty evidence. For chronic burn scars, synthesized evidence from six studies (n = 241) indicates improvements in clinician-rated scar scales and histologic architecture when injected fat grafting is used, particularly when combined with fractional laser for facial scars (Lesmanawati, 2024). Symptomatically, higher satisfaction and some improvements in hand movement were reported in six studies (n = 241), but effects on function, pain, or itch were mixed (Lesmanawati, 2024). Divergent findings were noted in pediatric populations within a synthesis of six studies (n = 241), where one randomized trial found no improvement compared to saline (Lesmanawati, 2024). Evidence for acute burns was confounded by the use of topical nanofat, which is outside the scope of minimally manipulated grafting (Lesmanawati, 2024).

Fistula management

The available systematic reviews provide insufficient evidence regarding the efficacy of minimally manipulated autologous fat grafting for fistula management. Reviews addressing perianal Crohn's fistulas and nonenteric cutaneous fistulas, four studies (n = 49) and seven studies (n = 13) respectively, predominantly synthesized studies that utilized techniques involving more than minimal manipulation, such as microfragmented fat or stromal vascular fraction (De Gregorio, 2023; Bonomi, 2025). Furthermore, in four studies (n = 49), the frequent use of concomitant surgical maneuvers confounds the attribution of effects (De Gregorio, 2023). Consequently, these reviews do not permit conclusions specific to minimally manipulated autologous fat grafting for these indications.

Systematic reviews and meta-analyses for injectable soft-tissue fillers

Vocal fold insufficiency (injection laryngoplasty)

Injectable soft tissue fillers consistently provide measurable functional gains in the treatment of unilateral vocal fold paralysis. A meta-analysis of 32 studies (n = 1,917) showed short- to medium-term improvement in patient-reported quality of life, maximal phonation time, and normalized glottal gap, with adverse events rare and transient (Alkhalifah, 2025). A broader meta-analysis of 82 studies reported a mean maximal phonation time gain of 4.71 seconds (postop: n = 1,781; pre n = 1,981), along with significant reductions in jitter and shimmer (Safia, 2024).

The timing of intervention and the material used are major predictors of benefit (Safia, 2024). Early injection laryngoplasty, six months or less, reduced the relative risk of subsequent permanent thyroplasty to 0.25 across 275 pooled cases, with mean injection time 4.5 months (Vila, 2018; Safia, 2024). Reviews focused on hyaluronic acid confirm durability clustered at six to 12 months with inflammatory complications in 1.47% of 476 treated individuals (Švejdová, 2022). Comparative studies reinforce clinical effectiveness relative to alternatives; 17 head-to-head studies showed no consistent superiority of injection laryngoplasty versus thyroplasty, arytenoid adduction, or reinnervation across perceptual, acoustic, or laryngoscopic outcomes (Siu, 2016; Safia, 2024).

Human immunodeficiency virus-associated facial lipoatrophy

Injectable soft tissue fillers demonstrate consistent safety, efficacy, and durability for restoring facial volume in human immunodeficiency virus-associated facial lipoatrophy. Multiple fillers improve contour

and quality of life but differ in durability and complication profiles (Jagdeo, 2015). Six observational studies of hyaluronic acid showed consistent volume restoration at six and 12 months, offering a safe, reversible option for short- to medium-term use (Jagdeo, 2015).

Longer-lasting fillers extend benefit but may increase complication rates. Poly-L-lactic acid, supported by three randomized trials and 20 observational studies, provides more durable correction, sustaining tissue depth gains at 48 weeks in randomized cohorts (n = 130), but carried a higher risk of nodule formation (Jagdeo, 2015). Calcium hydroxylapatite also offers predictable medium-term benefit (Jagdeo, 2015). In contrast, polyalkylimide gel demonstrated high infectious complication rates, 3.3% to 19%, in long-term observational series (Jagdeo, 2015).

References

On 9/8/2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were Autologous fat grafting, fat transfer, lipofilling, adipose tissue graft, dermal fillers, injectable fillers, soft tissue fillers, hyaluronic acid, poly-L-lactic acid, calcium hydroxylapatite, collagen injection. We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

9/15/2025initial review date and clinical policy effective date: TBD

Balloon Spacer Devices for Management of Massive Rotator Cuff Tears

Clinical Policy ID: **CCP. 1549**

Recent review date: **9/30/2025**

Next review date: **1/31/2027**

Policy contains: **subacromial balloon spacer, biodegradable balloon spacer, shoulder spacer, rotator cuff tear, massive irreparable rotator cuff tear, rotator cuff injuries.**

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Coverage policy

Subacromial balloon spacer implantation for the treatment of massive, irreparable rotator cuff tears is considered investigational/not clinically proven and therefore not medically necessary.

Background

Rotator cuff tears affect adults across their lifespan and become more common with age (Varacallo, 2024). Population studies that include people without symptoms estimate full-thickness tears in roughly 20% of adults (Yamamoto, 2010). Prevalence rises further with aging, with more than 50% of people in their 80s showing rotator cuff changes on imaging (Tempelhof, 1999). Many tears remain silent at first, which delays diagnosis and allows deterioration of tendon and muscle (Keener, 2015).

What defines a massive, irreparable rotator cuff tear? Clinicians use size and anatomy to define massive tears, which account for about 10% to 40% of diagnosed full-thickness tears (Agout, 2018). A tear larger than five centimeters or involving two or more cuff tendons qualifies as massive (Sánchez-Losilla, 2022). Tears that are considered irreparable show a 50% or more fatty change on magnetic resonance imaging, tendon retraction to the socket edge, or a space between the acromion and the ball of the upper arm bone of less than seven millimeters on radiographs (Sánchez-Losilla, 2022). These markers signal tissue that surgeons cannot mobilize back to bone with acceptable tension and that will not regain function after a standard repair (Virk, 2016).

Reverse total shoulder arthroplasty is the most common operation when shoulder function is lost and the cuff cannot be restored (Virk, 2016). Surgeons place the ball on the shoulder blade and the socket on the upper arm so the deltoid muscle can lift the arm in place of the torn cuff (Berliner, 2024). They select this option most often for older adults or for any individual with arthritis or pseudoparalysis who needs reliable pain relief and overhead use of the arm (Berliner, 2024). The tradeoff in reverse total shoulder arthroplasty is the use of a prosthesis with long-term risks, so surgeons reserve it for individuals whose goals cannot be achieved with repair, partial repair, or tendon transfer (Virk, 2016).

For adults who prefer to preserve the native joint when repair is not feasible and arthroplasty is undesirable, surgeons may use a subacromial balloon spacer to restore spacing and improve mechanics (Sheean, 2024). This biodegradable implant sits between the acromion and the upper arm bone, helps recentre the ball, and reduces painful contact when the rotator cuff cannot stabilize the joint (Sheean, 2024). It dissolves over about one year and may be combined with other limited procedures to control pain and maintain motion (Sheean, 2024). In the United States, the Food and Drug Administration issued a De Novo classification in 2021 for a resorbable shoulder spacer for adults 65 years or older with massive, irreparable tears and mild to moderate arthritis, which guides labeling, testing, and use (Food and Drug Administration, 2021).

Findings

Evidence for biodegradable subacromial balloon spacers is mixed. Observational studies show that individuals who received these spacers experienced substantial improvements from baseline at 24 months: Constant-Murley scores increased from 34.8 to 67.9, visual analog pain scores decreased from 6.6 to 2.0, flexion improved from 108.5° to 151.2°, and approximately 83% achieved the minimal clinically important difference. However, comparative meta-analyses do not demonstrate superiority of the spacers over partial repair or arthroscopic debridement, with negligible effects on pain (mean difference -0.11) and motion. Randomized data are comparator dependent: adding a spacer to debridement yields worse function at 12 months and inferior 24-month quality of life, whereas outcomes are comparable to partial repair with shorter operative time and modest early advantages in elevation. Methodological limitations, heterogeneity, and sparse long-term threshold outcomes temper certainty. Guideline discordance mirrors these patterns, with the National Institute for Health and Care Excellence advising against routine use outside trials when debridement is suitable, and the American Academy of Orthopaedic Surgeons offering a consensus option for selected individuals without glenohumeral osteoarthritis.

Guidelines

Clinical practice guidelines present divergent recommendations regarding the use of biodegradable subacromial balloon spacers for the treatment of irreparable rotator cuff tears, reflecting the conflicting nature of the available evidence. The National Institute for Health and Care Excellence recommended against biodegradable subacromial spacer use when arthroscopic debridement is suitable, and restricted use to research when debridement is not suitable. The committee based this chiefly on a U.K. multicenter randomized clinical trial in which debridement plus spacer was inferior to debridement alone at 12 months on Oxford Shoulder Score and Constant score, and the trial was stopped for futility. Evidence syntheses and a randomized clinical trial against partial repair show short- to mid-term improvements in pain and function within the group after spacer implantation, but long-term benefits remain uncertain (National Institute for Health and Care Excellence, 2023). Conversely, the American Academy of Orthopedic Surgeons states that balloon spacers may be considered for massive, irreparable rotator cuff tears without arthritis, but only as a consensus-based option — the lowest evidence grade — given inconsistent evidence and the need for individualized decision-making (American Academy of Orthopedic Surgeons, 2025). This consensus rating acknowledges the absence of reliable evidence due to significant heterogeneity and conflicting results among existing studies, including randomized trials that show both favorable and unfavorable outcomes for the device, depending on the comparator (American Academy of Orthopedic Surgeons, 2025).

Systematic reviews

Symptom and function improvement versus comparative advantage

Across the literature, balloon spacers have been shown to reliably produce within-group gains but not superiority over established options. Kunze synthesized contemporary reports and found high proportions of individuals achieving minimal clinically important difference on the Constant-Murley score (83%), American Shoulder and Elbow Surgeons score (83% – 87.5%), Oxford Shoulder Score (78% – 87%), and numeric pain rating scale (69% – 74%) from a pooled cohort (n = 748; spacer subset n = 379). However, achievement of a patient-acceptable symptom state and substantial clinical benefit was inconsistent and methodologically heterogeneous, limiting the ability to infer absolute outcome levels and durability of balloon spacers (Kunze, 2023).

In a head-to-head pooled comparison, Sandler reported greater visual analog scale pain reduction with debridement (adjusted mean difference -0.7 , $P < 0.001$) and larger Constant-Murley gains ($+5.5$, $P < 0.001$), with neither study arm meeting the patient-acceptable symptom state threshold for pain (Sandler, 2024). The randomized evidence aligns with other researchers' findings. Metcalfe found Oxford Shoulder Scores favored debridement at 12 months (mean 34.3 versus 30.3; adjusted difference -4.2 , 95% confidence interval -7.8 to -0.6 , $P = 0.026$) in a trial that was stopped early for futility (Metcalfe, 2022).

Movement domains and what they mean clinically

Improvements in movement occurred with both approaches, but advantages differed by plane and did not change the overall comparative picture. Sandler observed relatively larger gains in abduction and external rotation with spacers, whereas forward flexion gains were larger with debridement. These directional differences did not translate into superior overall function for spacers (Sandler, 2024). Metcalfe reported no clinically meaningful advantage for spacers across secondary outcomes despite standardized rehabilitation and blinding, reinforcing that plane-specific gains do not overcome the absence of comparative benefit (Metcalfe, 2022).

Safety and durability

Device-specific risks and uncertain durability weigh against routine adoption. In Sandler, nearly one-half of spacer complications were migration or rupture, one-quarter of spacer reoperations were device revision or removal, and mean time to reverse shoulder arthroplasty was shorter after spacers than after debridement (Sandler, 2024). Kunze's review emphasizes heterogeneity in thresholds and designs that can inflate apparent success in single-arm reports, underscoring the need for consistent definitions and comparative designs before concluding durable benefit (Kunze, 2023). Metcalfe's masked, intraoperative randomization and standardized rehabilitation minimize bias and provide the highest-quality signal to date that spacers do not confer comparative benefit (Metcalfe, 2022).

Meta-analyses

Comparative evidence does not show an advantage of the subacromial balloon spacer over alternative surgery (Daher, 2023; Sirignano, 2024). Daher's meta-analysis pooled three comparative studies (n = 311) and found no significant differences across pain, quality of life, function, or range of motion; for example, the pooled mean difference for visual analog scale pain was -0.11 (95% confidence interval -0.48 to 0.27), and range of motion contrasts were negligible for abduction (-2.6°) and forward elevation (-0.4°) (Daher, 2023). Sirignano's systematic review included twenty-seven studies spanning both comparative and noncomparative designs, with only six being comparative, which explains the difference between the total sample (n = 894) and the smaller pooled comparative analyses; its metaanalysis likewise reported a pooled visual analog scale effect of -0.11 (95% confidence interval -0.44 to 0.22) and no overall difference in active shoulder flexion (overall effect size 0.11, p=0.87) (Sirignano, 2024).

This pattern contrasts with noncomparative cohorts, which consistently showed within-group gains after balloon spacer implantation at 12 and 24 months in pain, function, and motion, even as pooled head-to-head comparisons remained null (Sirignano, 2024; Daher, 2023). Methodological quality was fair as measured by the Modified Coleman Methodology Score (mean 61.4 ± 11), and heterogeneity and small samples with clinically diverse patients limited precision (Sirignano, 2024; Daher, 2023). Outcomes may be better in carefully selected patients who can re-establish the glenohumeral force couple and who adhere to prescribed physical therapy; closer alignment between surgical and rehabilitation teams, with clearer reporting of postoperative rehabilitation, may further improve results (Sirignano, 2024).

Other evidence

Across studies, individuals improved meaningfully from baseline. In a level-one randomized controlled trial, use of a subacromial balloon spacer was compared with arthroscopic partial repair. The use of the spacer produced similar improvements to partial repair in the American Shoulder and Elbow Surgeons score and the Western Ontario Rotator Cuff Index without between-group pain differences, but the

Constant-Murley score favored the balloon spacer at week six and month 24 ($P = 0.021$ and $P = 0.05$), and forward elevation favored the balloon spacer at every measured time point through 24 months ($P \leq 0.0048$ after week six) (n = 184) (Verma, 2022). In a retrospective series, the adjusted Constant-Murley score rose to 76.0 at approximately 33 months with gains in elevation, abduction, and external rotation (n = 39 shoulders) (Deranlot, 2017).

In a multicenter randomized controlled trial with debridement as the comparator, debridement alone outperformed debridement plus balloon on the Western Ontario Rotator Cuff Index and the Patient Global Impression of Change at 24 months, with the Oxford Shoulder Score trending the same way; range of motion data was not collected (n = 117) (Hague, 2025). In a separate report, adverse events and reoperations were infrequent and balanced in the randomized controlled trials, and no device-related serious events were reported (Verma, 2022). Operative time was shorter with the balloon spacer than partial repair, 44.6 minutes versus 71.2 minutes ($P < 0.0001$) (Verma, 2022). Operative time was shorter with InSpace than partial repair, 44.6 versus 71.2 minutes ($P < 0.0001$) (Verma, 2022). Deranlot reported one revision for spacer migration and limited radiographic progression, with Hamada advancing one stage in four shoulders and three stages in one (Deranlot, 2017).

References

On 9/4/2025, 2025 we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were subacromial balloon spacer, biodegradable balloon spacer, shoulder spacer, rotator cuff tear, massive irreparable rotator cuff tear, reverse shoulder arthroplasty, tendon transfer, arthroscopic debridement. We included the best available evidence according to established evidence hierarchies (typically systematic reviews, metaanalyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

9/4/2025: initial review date and clinical policy effective date: [ccp.04_effective_date]

Pediatric bed enclosures

Clinical Policy ID: CCP.1537 Recent

review date: 12/2025

Next review date: 4/2027

Policy contains:Autism; bed enclosure; Cubby Bed; insomnia; neurodevelopmental disorder; sensory bed; sleep disorder.

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case by case basis, by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

A pediatric bed enclosure is clinically proven and, therefore, may be medically necessary to provide a safe and secure sleeping environment in the home for members who are at risk of falls, wandering, or self-harm (Harris, 2015; Sherburne, 2017).

Limitations

A pediatric bed enclosure is contraindicated in members who (Harris, 2015):

- Are violent, combative, self-destructive, suicidal, or claustrophobic.
- Have multiple intravenous lines, urinary catheters, or medical tubing.
- Become increasingly distressed after being placed in the bed.

The following items are considered nonhospital beds or accessories items and not medically necessary, as the clinical value and long-term clinical outcomes have not been established:

- Beds sold as traditional furniture including adjustable beds (e.g., a Craftmatic Adjustable Bed, Simmons Beautyrest adjustable bed, Electrometric adjustable bed, and Sealy Posturepedic Bed).
- Accessory items or services (e.g., technology hubs, travel cases, memory foam mattresses, other bed accessories such as bed linens, tables, and pillows) that do not contribute meaningfully to the treatment of an illness or injury or the functioning of a malformed body part.
- Upgrades for aesthetic purposes or upgrades as part of an enclosed bed purchase that do not meet the rules for durable medical equipment, including, but not limited to:
 - Special lights, sounds, fans, cameras, two way talk monitors, vibration pads, or weighted blankets.
 - Custom wood types, finishes, or engravings, or special coverings on the outside of the bed.

- Custom upgrades where lower cost alternatives are readily available.

Alternative covered services

- Cognitive behavioral therapy.
- Pharmacotherapy.
- Parental education.
- Door locks and door alarms (may be noncovered services).

Background

Neurodevelopmental disorders are a group of conditions caused by changes in early brain development that affect brain processing, resulting in impairments in personal, social, academic, or occupational functioning (American Psychiatric Association, 2025). Sleep disorders are common among people with neurodevelopmental disorders, which can severely impact the quality of life and sleep of the affected individual and their caregivers. Contributing factors include environmental influences, caregiver-related factors, and disease-related etiologies (Blackmer, 2016).

Among children with autism spectrum disorder, behavioral factors, such as inability to self-calm, communication impairment, sensory processing issues, circadian sleep–wake cycle abnormalities, and chemical and metabolic mechanisms may contribute to sleep disturbances. Children with autism spectrum disorder, in particular, may have wandering tendencies (Johnson, 2024).

Neurodiverse children who are able to climb out of their beds are at risk of falls, wandering, and subsequent injury. A bed enclosure, also called a safety bed, canopy bed, or child-safe bed, is a fully enclosed canopy designed to prevent children from leaving their bed at night without supervision. A bed enclosure allows the patient to remain in a safe environment without the need for physical or chemical restraints, which may be detrimental to development, and offers the caregiver uninterrupted sleep and peace of mind.

A sensory bed combines a sensory-blocking bed enclosure with control of lighting, sound, vibration, and ambient temperature to create a comfortable, customizable, and relaxing sleep environment. Sensory beds may include motion sensors or cameras for remote monitoring and a control panel accessible from a smart phone or tablet. Examples include the Cubby Bed™ with Technology Hub (Cubby Beds, Denver, Colorado) and the zPod® (Zpods Holdings LLC, Saint Peters, Missouri).

Findings

Therapeutic management of sleep disorders in neurodiverse children is based largely on clinical experience and small observational studies, limited by subjective outcomes and study design. Current guidelines and supportive evidence suggest cognitive behavioral therapy and melatonin appear to be the most effective interventions. There is insufficient evidence supporting the use of sensory beds or other bed accessories to alter sensory stimuli as an effective treatment for sleep disturbances.

Guidelines

The American Academy of Neurology issued recommendations for treating sleep disturbances in children and adolescents with autism spectrum disorder. The strongest evidence supports the effectiveness of melatonin with or without cognitive behavioral therapy for improving multiple sleep outcomes compared with placebo. Evidence is insufficient to determine the effect of parental sleep-specific behavioral training. The guideline did not mention the use of sensory beds or sensory altering stimuli to improve sleep hygiene. The following recommendations received a Level B rating.

meaning the recommendations were associated with confidence in the rationale and a favorable benefit-risk profile (Williams Buckley, 2020):

- There should be an assessment of coexisting medical conditions and concomitant medications that may contribute to sleep disturbance.
- First-line therapy is cognitive behavioral therapy to improve sleep hygiene.
- Pharmacologic therapy (melatonin) may be indicated if managing coexisting conditions and adopting behavioral strategies are unsuccessful.
- There is insufficient evidence to support the routine use of weighted blankets or specialized mattress technology for improving disrupted sleep (Frazier, 2017), although weighted blankets appear safe and could be a reasonable nonpharmacologic approach for some individuals.

Evidence review

A summary of eight systematic reviews (38 total included studies) examined the efficacy of five interventions for treating sleep problems in children with autism spectrum disorder. Melatonin, behavioral interventions, and parent education/education programs appeared to be the most effective at ameliorating multiple domains of sleep problems compared with other interventions. There was insufficient evidence supporting pharmacologic treatments other than melatonin or alternative therapies (e.g., massage therapy, aromatherapy, and multivitamin and iron supplementation). The effect of polytherapeutic approaches requires further study (Cuomo, 2017).

For managing sleep disorders in children with neurodevelopmental disorders, the complexity of diagnosis and lack of high-quality evidence prevents a consistent approach to therapy. The initial approach should include evaluation and resolution of contributing or exacerbating factors of insomnia, including sleep hygiene, prior to initiating pharmacologic treatment. Iron supplementation, melatonin, and less common interventions (e.g., clonidine, gabapentin, hypnotics, trazodone, and atypical antipsychotics) may be prescribed. However, the heterogeneity of neurodevelopmental disorders and the lack of available data prevent determining the optimal choice of therapy. Ultimately, the medication with the least risk of toxicity and/or possibility of drug–drug interactions should be chosen (Blackmer, 2016; Johnson, 2024).

Sensory beds

The evidence for sensory bed technology is limited to one preliminary cross-over trial of the Sound-toSleep™ mattress (Kugona LLC, Lake Forest, IL) in children with autism (n = 45) (Frazier, 2017). The Sound-to-Sleep mattress technology embeds vibrations into the mattress corresponding to a sound source of the child's choosing. The Sound-to-Sleep mattress was generally well-tolerated among children and resulted in parent-reported improvements in sleep quality in the short-term. It may result in higher short-term sleep efficiency (i.e., the percentage of time spent asleep while in bed) over two weeks of use (78.27% when mattress was turned on versus 75.45% turned off, raw mean difference = 2.82%, 95% confidence interval 1.14 to 4.50). However, there was no statistically significant improvement in other measures of sleep continuity such as sleep onset latency (i.e., amount of time from lights turned off until the onset of any sleep stage), wake after sleep onset (i.e., the time individuals spend awake after sleep onset and before sleep offset), or total sleep time (i.e., sleep duration during a given sleep period time). Adverse effects were not described (Frazier, 2017).

A new systematic review of non-pharmacological treatments of sleep disorders in autistic children and adolescents without intellectual disability identified no other published studies of sensory beds (Vargas, 2025).

Pediatric bed enclosures

The evidence supporting the use of pediatric bed enclosures is limited to inpatients requiring some kind of restraint to ensure their safety. In one randomized controlled trial (n = 49 total), a bed enclosure was effective and more acceptable to relatives and providers than standard restraints, although there was no difference between groups in level of agitation, length of stay, time in restraints, or total dose of medication (Nawaz, 2007).

A retrospective chart review of 208 pediatric enclosure bed encounters in an acute care setting over a two-year period found children with new-onset cognitive impairment were more likely to incur falls, skin breakdown, and injury during use of the enclosure bed. However, an enclosure bed was reasonable for certain children to ensure their safety (Sherburne, 2017).

In one institution's experience with enclosure beds used for more than 200 inpatients, no patient falls or injuries occurred, and sitter expenses decreased. Enclosure beds were incorporated into some home care plans for patients with agitation secondary to dementia and for pediatric patients with significant chronic neurologic or behavioral problems as an option for fall prevention and patient safety. The main benefit of using an enclosure bed at home was giving caregivers a respite period from caring for the child by providing a safe environment (Harris, 2015).

The inpatient experience with bed enclosures offers some insight into appropriate use at home. To be considered for the enclosure bed, the patient must be at high risk for falling and must demonstrate one or more of the following characteristics: impulsiveness; agitation; inability or unwillingness to ask for assistance or respond to redirection; unsteady gait; or wandering behavior. An enclosure bed is contraindicated for (Harris, 2015):

- Patients who are violent, combative, self-destructive, suicidal, or claustrophobic.
- Patients with multiple intravenous lines or urinary catheters.
- Patients who become increasingly distressed after being placed in the bed.
- Patients with a history of falling alone.

In 2024, we updated the references with no policy changes warranted.

In 2025, we updated the references and added one systematic review to the policy. We modified the coverage criteria to expand on durable medical equipment considered not medically necessary.

References

On September 11, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "bed enclosure," "autistic disorder (MeSH)," "behavior therapy (MeSH)," "music therapy," "sensory bed," "sound therapy," "chromotherapy," "escape," and "autism." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

- 11/2023: initial review date and clinical policy effective date: 12/2023
- 11/2024: Policy references updated.
- 12/2025: Policy references updated. Coverage modified.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1537
This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description

Skin Substitutes for Chronic Wounds

Clinical Policy ID: CCP. 1552

Recent review date: 10/31/2025 Next

review date: 2/28/2027

Policy contains: diabetic foot ulcer, skin substitutes (cellular, acellular), venous leg ulcer, thermal burns.

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case-by-case basis, by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

Skin substitutes (i.e., cellular or acellular products) are clinically proven and, therefore, may be medically necessary for cutaneous wounds and thermal burns when all general and indication-specific criteria below are met:

General (all indications)

- Coverage is contingent upon meeting all of the following general criteria:
- Partial or full-thickness cutaneous defect with a prepared wound bed (adequate debridement, clean, moisture-balanced) and no clinical signs of active infection (Eriksson, 2022).
- Managing the specific cause of the wound is required during treatment. This includes proven offloading (using a special cast, boot, or other device to take all pressure off the wound) for diabetic foot ulcers, and sustained compression (using special tight bandages or socks) for venous leg ulcers (Bus, 2024; Wound, Ostomy, and Continence Nurses Society, 2021).
- Nutritional status has been assessed and optimized to support healing (Eriksson, 2022).
- Objective perfusion assessment supports healing potential as defined for the specific indication below.
- One product at a time; no known hypersensitivity to the product source (Eriksson, 2022).
- The application technique and frequency must conform to the Food and Drug Administration-labeled instructions for use for the selected product.

Diabetic foot ulcers (neuropathic, non-ischemic)

Adjunctive use of cellular or acellular skin substitute products to promote ulcer closure is clinically proven and, therefore, may be medically necessary when all general criteria are met and:

- Adequate perfusion is documented: Suggested by any of toe pressure ≥ 30 mm Hg, skin perfusion pressure ≥ 40 mm Hg, or transcutaneous oxygen pressure > 25 mm Hg. Urgent vascular imaging and

consultation for revascularization must be considered if ankle pressure is <50 mm Hg, ankle-brachial index is < 0.5, toe pressure is < 30 mm Hg, or transcutaneous oxygen pressure is < 25 mm Hg. Anklebrachial index alone is unreliable in diabetes (Fitridge, 2023; Hinchliffe, 2020).

- The ulcer is a chronic, non-infected ulcer that extends through the dermis without exposed tendon, muscle, capsule, or bone. It has failed to show $\geq 50\%$ area reduction after ≥ 4 weeks of optimized standard care (serial debridement, moisture balance, infection control, and effective offloading). The wound must also meet the minimum chronicity duration specified in the selected product's labeling (e.g., greater than 3 weeks for Apligraf; greater than 6 weeks for Dermagraft) (Lavery, 2024; International Working Group on the Diabetic Foot, 2023).
- Glycemic management is being addressed and optimized (Lavery, 2024).
- No untreated osteomyelitis at the ulcer site and no active Charcot process involving the ulcer surface. Manage infection or Charcot before applying a skin substitute (Lavery, 2024; International Working Group on the Diabetic Foot, 2023).

Nonhealing dermal wounds (non-pressure)

Adjunctive use of cellular or acellular skin substitute products is clinically proven and, therefore, may be medically necessary when all general criteria are met and:

- Adequate perfusion is documented: Suggested by any of toe pressure ≥ 30 mm Hg, skin perfusion pressure ≥ 40 mm Hg, or transcutaneous oxygen pressure ≥ 25 mm Hg. Urgent vascular imaging and consultation for revascularization must be considered if ankle pressure is < 50 mm Hg, ankle-brachial index is < 0.5, toe pressure is < 30 mm Hg, or transcutaneous oxygen pressure is < 25 mm Hg. Anklebrachial index alone may be unreliable in diabetes (Fitridge, 2023; Hinchliffe, 2020).
- Non-infected, partial- or full-thickness traumatic, postsurgical, or ischemic venous mixed ulcers fail to improve after more than 4 weeks of optimized care as above. Selection should follow labeling and objective monitoring (Eriksson, 2022).

Thermal burns

Use of skin substitute products in acute thermal burns is clinically proven and, therefore, may be medically necessary when all general criteria are met and:

- Partial- or deep partial-thickness thermal burns have undergone appropriate excision and hemostasis; no burn wound infection is present; autograft is not immediately available or is being staged; products are used for temporary coverage, donor-site optimization, or to reduce autograft burden per labeling and evidence (Hicks 2019; van den Bosch, 2025).

Venous leg ulcers

Adjunctive use of cellular or acellular skin substitute products with sustained therapeutic compression is clinically proven and, therefore, may be medically necessary when all general criteria are met and:

- Adequate arterial perfusion is confirmed: Apply standard compression if ankle-brachial index is ≥ 0.8 ; consider modified/light compression if ankle-brachial index is 0.5–0.8; do not initiate compression if anklebrachial index is < 0.5 or > 1.3 (Wound, Ostomy, and Continence Nurses Society, 2021).

- A chronic, non-infected partial or full-thickness ulcer has failed to show meaningful improvement (e.g., <50% area reduction) after ≥ 4 weeks of optimized standard care with sustained therapeutic compression, appropriate debridement, infection control, and moisture balance (O'Donnell, 2014; Marston, 2016; Wound, Ostomy, and Continence Nurses Society, 2021).
- Sustained therapeutic compression must continue during treatment (O'Donnell, 2014; Wound, Ostomy, and Continence Nurses Society, 2021).

See the Appendix for representative products by class and the indications covered under this policy; examples are provided for illustrative purposes.

Limitations

Other uses of skin substitute products are investigational/not clinically proven and, therefore, not medically necessary, including for the following:

- In those without documented offloading for a diabetic foot ulcer (Lavery, 2024) or without sustained therapeutic compression for a venous leg ulcer (O'Donnell, 2014).
- Those with uncontrolled infection, untreated ischemia below the thresholds defined in the indicationspecific criteria, or an unprepared wound bed (Hinchliffe, 2020), and those with known hypersensitivity to the product source (Snyder, 2020).
- For active vasculitides or autoimmune ulcerative conditions requiring primary systemic management (Eriksson, 2022).
- For routine use for pressure ulcers (Gould, 2024).
- For prophylactic use on closed, intact skin or for cosmetic purposes (Snyder, 2020).
- Use on fully epithelialized wounds is also not medically necessary (Snyder, 2020).
- When more than one product is used simultaneously on the same wound (Snyder, 2020).
- If there is less than 50% area reduction after 4 weeks of product use, this indicates a need to change the approach (Lavery, 2024). Alternative covered services
- Optimized standard wound care: regular debridement, moisture balance, appropriate dressings.
- Offloading for diabetic foot ulcer: total contact casting or other irremovable knee-high devices when feasible.
- Compression therapy for venous leg ulcer: sustained, multilayer compression with edema control.
- Infection management: culture-guided therapy and source control; treat osteomyelitis when present.
- Vascular assessment and optimization, including revascularization when indicated by perfusion thresholds above.
- Metabolic and risk modification: glycemic management, smoking cessation, and nutrition optimization.
- Adjuncts for wound bed preparation: negative pressure wound therapy and biofilm control as indicated.

Background

Chronic wounds, including diabetic foot ulcers, venous or arterial ulcers, neuropathic ulcers, and pressure ulcers, persist beyond four to six weeks and often fail to reduce in size with standard wound care. These wounds are common (affecting roughly 2 % of the U.S. population). Because chronic wounds do not heal properly, complications such as infection, osteomyelitis, amputation, and sepsis arise; mortality rates for diabetic foot ulcers can be comparable to those of some cancers. Skin substitutes are considered advanced therapies rather than first-line treatments (Vecin, 2023).

Skin and soft tissue substitutes are a diverse group of materials designed to promote wound healing and restore the structural and functional integrity of the skin and soft tissue. They are utilized when standard wound care fails or autologous grafting is infeasible. These products function by providing a protective barrier, maintaining moisture, and offering a scaffold, growth factors, or cellular components that support tissue regeneration. Chronic wounds, such as diabetic foot ulcers and venous leg ulcers, along with acute wounds like thermal burns, present significant clinical challenges and disease burden (Halim, 2010)

A skin substitute is defined as a cellular (containing living cells) or acellular (without living cells) matrix. Sources include human tissue (autologous or allogeneic, such as cadaveric dermis or amniotic/chorionic membranes), non-human tissue (xenographic, such as porcine or bovine sources), synthetic polymers, or biosynthetic composites (Capo 2014; Vecin, 2023). Products are further categorized by the layers they replace (dermal, epidermal, or bilayer constructs). The majority of available products are acellular dermal substitutes derived from placental membranes or animal tissue (Snyder, 2020).

Clinical variables influencing product selection include wound etiology, size, depth, duration, vascular status, and infection control. Appropriate use requires documented failure of prior standard care (typically 4 weeks), adequate site preparation (debridement), and ongoing adjunctive care (offloading for diabetic foot ulcers, compression for venous leg ulcers). Regulatory pathways vary; products may be regulated as medical devices (Premarket Approval or 510(k) clearance) or as Human Cells, Tissues, and Cellular or Tissue-based Products (HCT/Ps) (Vecin, 2023).

Findings

Guidelines and evidence reviews agree that skin substitutes are adjuncts to optimized standard care, adequate perfusion, and infection control, with escalation typically occurring when $\geq 50\%$ area reduction is not achieved by 4 weeks, and with one product used at a time. For diabetic foot ulcers, meta-analyses and society guidelines indicate higher complete-closure rates compared to standard care when used in conjunction with effective offloading and after infection is treated, with safety profiles similar to those of standard care. For venous leg ulcers and nonhealing dermal wounds, systematic reviews report an adjunctive benefit when paired with sustained compression and objective monitoring. However, the effects are heterogeneous and influenced by the chronicity of the ulcer. In acute thermal burns, randomized trials and meta-analyses support the selective use of these matrices for temporary coverage and donor-site sparing, with improved scar outcomes, but slower early epithelialization for some matrices. In contrast, guidelines do not support routine use for pressure ulcers due to limited evidence.

Guidelines

Chronic wound management aims to restore cutaneous structural and functional integrity (Agency for Healthcare Research and Quality [Snyder, 2020]). Yet, chronic wounds frequently stall in the inflammatory phase, representing a failure in the normal healing sequence (Wound Healing Foundation [Eriksson, 2022]). Professional guidelines establish a hierarchical approach, reserving advanced therapies, such as skin substitutes, for wounds that fail to respond despite optimized local wound environments. The Wound Healing Foundation [Eriksson, 2022] emphasizes that advanced modalities require meticulous wound bed preparation through thorough debridement of nonviable tissue and biofilm (Wounds International Consensus Document on the Use of Wound Antiseptics in Practice [Nair, 2023]), with the International Working Group on the Diabetic Foot

[Schaper, 2023] advising that skin substitutes be deferred until infection, including osteomyelitis, is controlled; offloading should continue during infection management.

Professional societies define treatment escalation using objective metrics: failure to achieve a 50% reduction in wound area after 4 weeks of optimized, etiology-specific standard care predicts long-term non-healing and justifies consideration of advanced therapy (Wound Healing Foundation [Eriksson, 2022]; Agency for Healthcare Research and Quality [Snyder, 2020]). This temporal benchmark, validated across multiple guidelines, signals when adjunctive interventions become appropriate. Randomized controlled trials do not support the routine use of biologically active products as first-line treatment for diabetic foot ulcers; their use is applicable only after documented failure of optimized care with confirmed healing potential (International Working Group on the Diabetic Foot [Chen, 2023]). Guidelines recommend using one adjunct at a time, as efficacy trials evaluate products individually against optimized care (Agency for Healthcare Research and Quality [Snyder, 2020]).

Adequate tissue perfusion remains fundamental to healing potential, necessitating rigorous vascular assessment before initiating advanced therapies (Wound Healing Foundation [Eriksson, 2022]). Because ankle–brachial index can be unreliable in diabetes, confirm distal perfusion: toe pressure ≥ 30 mmHg or TcPO₂ ≥ 25 mmHg indicate adequate healing potential, with values below prompting urgent imaging and revascularization (International Working Group on the Diabetic Foot [Fitridge, 2023]); where available, skin perfusion pressure ≥ 40 mmHg also supports healing potential (Wound, Ostomy and Continence Nurses Society [Bonham, 2022]).

Advanced therapies cannot compensate for unaddressed underlying wound etiology. For neuropathic diabetic foot ulcers, effective mechanical offloading is foundational (International Working Group on the Diabetic Foot [Bus, 2024; Schaper, 2024]); for venous leg ulcers, sustained therapeutic compression is a prerequisite and must continue throughout treatment (Wound Healing Society [Marston, 2016]; Wound, Ostomy and Continence Nurses Society [Bonham, 2022]). Non-adherence to these etiology-specific measures renders advanced modalities inappropriate (International Working Group on the Diabetic Foot [Schaper, 2024]; Wound Healing Society [Marston, 2016]). The Wound Healing Society's 2023 update [Lavery, 2024] reinforces this hierarchy, maintaining Level I evidence for certain cellular and acellular matrices in chronic diabetic foot ulcers that are unresponsive to standard therapy, while emphasizing the use of single products with continued objective monitoring for early non-response.

Evidence strength varies by wound type. For pressure ulcers, the Wound Healing Society [Gould, 2024] does not recommend routine use of skin substitutes, given limited and inconsistent evidence. Conversely, cellular and acellular matrices may be considered for diabetic foot or venous leg ulcers failing optimized standard care (lacking $\geq 50\%$ area reduction at four weeks) when perfusion is adequate and infection controlled (Agency for Healthcare Research and Quality [Snyder, 2020]; International Working Group on the Diabetic Foot [Schaper, 2024]). The application is not indefinite; failure to demonstrate significant progress within the initial weeks necessitates discontinuation of the product and a reassessment of the strategy (Wound Healing Foundation [Eriksson, 2022]). Across all indications, guidelines converge on foundational requirements: adequate perfusion, infection control, and optimized standard care must precede any advanced intervention.

Evidence review

Efficacy in wound closure and healing kinetics

Skin substitutes significantly enhance the probability of complete healing in chronic non-pressure wounds compared to standard care; however, their impact on healing velocity in acute burns is more variable, depending

on the material and wound depth. In the management of diabetic foot ulcers, a meta-analysis across twenty-nine randomized controlled trials ($n = 3,109$) demonstrated improved complete healing, yielding a pooled odds ratio of 2.9 versus standard care; this effect was robust, showing no modification by baseline age or wound size, and remained consistent (odds ratio 2.7) after correction for publication bias (Lu, 2025). Convergent evidence from a broad review of twenty-two randomized controlled trials ($n = 1,668$ participants with reported enrollment) spanning diabetic foot ulcers, venous leg ulcers, and pressure ulcers confirmed higher closure rates and shorter time to closure when utilizing advanced biologics such as amniotic membranes, dermal matrices, and bilayer collagen templates compared to standard care (Snyder, 2020). While effects in venous leg ulcers were directionally similar, the results exhibited greater heterogeneity, with benefits appearing more concentrated in ulcers of shorter duration (Snyder, 2020).

In the context of acute burns, the impact of acellular dermal substitutes on wound healing kinetics demonstrates adequate incorporation but often delayed initial epithelialization compared to standard autografting. A metaanalysis indicated that collagen-elastin matrices significantly delayed re-epithelialization at 4 to 7 days compared to split-thickness skin grafts alone (Mean Difference -7.30%; $p = 0.02$) (van den Bosch, 2024). This delay was accompanied by non-significant trends toward lower graft take (Mean Difference -3.13%) and increased need for regrafting (Odds Ratio 1.99) (van den Bosch, 2024). For acute full-thickness burns treated with bilayer dermal regenerative matrices ($n = 800$), the mean template take was 86%, necessitating subsequent grafting at an average of 24.2 days (Hicks, 2019). An exception involves specific xenografts in partial-thickness burns; compared to silver sulfadiazine ($n = 115$), acellular fish skin reduced the mean re-epithelialization time (9.7 versus 10.2 days) (El Araby, 2025).

Comparative effectiveness of cellular versus acellular substitutes

The comparative effectiveness between cellular and acellular products does not reveal a uniform advantage for either category across wound types, suggesting that efficacy is context-dependent. In the management of chronic wounds, six head-to-head randomized comparisons ($n \geq 436$ across trials with reported enrollment) illustrated varied outcomes (Snyder, 2020). For instance, an acellular urinary bladder matrix demonstrated comparable results to a cellular dermal substitute in terms of closure rates, time to closure, and six-month recurrence rates (Snyder, 2020). In another comparison, a dehydrated amniotic and chorion membrane (acellular) outperformed a living bilayer construct (cellular) for twelve-week closure while requiring fewer graft applications (Snyder, 2020). Comparisons between two different cellular products were broadly similar, noting only a small-wound subgroup advantage for a cryopreserved placental membrane (Snyder, 2020). In the context of burns, cellular substitutes, such as Cultured Skin Substitutes, offer specific advantages in resource utilization by significantly reducing the requirement for donor skin harvesting through increased expansion ratios compared to meshed autografts (ratio 67 versus 4; $p < 0.01$); however, this benefit is balanced against increased graft loss observed between postoperative days 7 and 14 ($p < 0.05$) (Putri, 2024).

Long-term scar quality and functional outcomes

The application of dermal substitutes consistently demonstrates improvements in long-term scar quality and function following burn injury and reconstruction. Following acute burn injury, a meta-analysis comparing acellular dermal matrices with split-thickness skin grafts alone revealed a statistically significant improvement in Vancouver Scar Scale scores at 6 months (Mean Difference -1.95; $p < 0.01$) (van den Bosch, 2024). This finding aligns with results from three randomized controlled trials ($n=128$), which also demonstrated a significant improvement in Vancouver Scar Scale scores when comparing combined skin substitutes and skin grafts to skin grafts alone (Standardized Mean Difference 1.38; 95% Confidence Interval 0.13–2.63; $p=0.03$) (Putri, 2024). The

mean postoperative Vancouver Scar Scale score following acute burn treatment with dermal regenerative matrices was reported as 2.3 (Hicks, 2019). While objective elasticity measurements (Uf-ratio) for collagenelastin matrices did not show statistically significant improvements over split-thickness skin grafts alone at 12 months (Mean Difference -0.05), subjective reports frequently noted enhanced pliability (van den Bosch, 2024; Putri, 2024).

Dermal substitutes are also utilized in burn scar reconstruction (n = 284) to address contractures, particularly in functional areas such as the neck, hand/wrist, and axilla (Hicks, 2019). Functional outcomes following reconstructive surgery are favorable; across four studies (n = 42), 95% of patients demonstrated objective improvements in range of motion following contracture release utilizing dermal regenerative matrices (Hicks, 2019). In these reconstructive settings, graft incorporation was higher than in acute applications (mean template take 95%; subsequent graft take 93%) (Hicks, 2019). However, quantitative outcomes regarding scar contraction reveal differences between materials; a comparison showed that collagen-elastin matrices resulted in statistically significantly higher contraction compared to bilayer collagen-glycosaminoglycan matrices (Mean Difference +25.21%; p = 0.0003), although this finding was confounded by heterogeneity in surgical application techniques (van den Bosch, 2024).

Safety profiles and patient experience

The safety profiles of skin substitutes are generally comparable to those of standard care across various wound etiologies. However, complication rates vary by material and clinical context, with certain materials offering advantages in terms of patient comfort and resource utilization. In chronic wound management, adverse event profiles were similar between advanced biologics and standard care, with infection and cellulitis being the dominant complications (Snyder, 2020). In the acute burn setting, adverse events associated with dermal regenerative matrices were reported across 72 studies (n = 1084), occurring at an overall rate of 13% (Hicks, 2019). The most frequent complication was infection (4.6%), commonly caused by *Staphylococcus aureus* and *Pseudomonas aeruginosa*; other complications included graft loss, hematoma, and contracture (Hicks, 2019). Patient-reported outcomes indicate advantages for specific materials in partial-thickness burns; acellular fish skin grafts were associated with significant reductions in pain compared to silver sulfadiazine (Visual Analogue Scale 20.5 versus 29.2) and silver-impregnated dressings (Visual Analogue Scale 13.96 versus 24.79) (El Araby, 2025). Furthermore, fish skin significantly decreased the number of dressing changes required (1.6 versus 4.9) compared to silver sulfadiazine (El Araby, 2025).

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Policy updates

9/30/2025 initial review date and clinical policy effective date: 10/31/2025 11/2025:

Policy created.

Appendix: product selection, details, and regulatory information

1. Purpose

This appendix provides a regulatory-verified framework to guide appropriate selection and continuation of advanced wound products for diabetic foot ulcers, venous leg ulcers, and thermal burns. It aligns product use with United States Food and Drug Administration labeling and establishes consistent decision rules for payer coverage determinations.

2. Scope

- Populations: Adults and children as permitted by Food and Drug Administration labeling for each product.
- Wound types:
 - Chronic ulcers: Diabetic foot ulcers and venous leg ulcers without exposed tendon, muscle, joint capsule, or bone (unless labeling explicitly permits).
 - Thermal burns: Partial-thickness, deep partial-thickness requiring surgery, full-thickness, and extensive burns as defined by Food and Drug Administration labeling.
- Required foundational care:

- Diabetic foot ulcer: Evidence-based offloading and infection control.
- Venous leg ulcer: Sustained therapeutic compression.
- All: Adequate perfusion, debridement as needed, moisture balance, and infection management.

3. Core Decision Principles

1. Food and Drug Administration Alignment First: Product selection must match the exact Food and Drug Administration-labeled indication (etiology, depth, duration, anatomic limits, population).
2. Evidence Hierarchy: Prefer Food and Drug Administration Premarket Approval, Biologics License Application, or Humanitarian Device Exemption products (Tier 1) when clinically appropriate; use 510(k) devices (Tier 2) when no Tier 1 option fits; reserve Human Cells, Tissues, and Cellular and Tissue-based Products (Tier 3) as the lowest tier, noting they are not Food and Drug Administration-approved for wound indications.
3. Clinical Eligibility Gate: Diabetic foot ulcers and venous leg ulcers must have documented failure of optimized standard care at four weeks unless a Food and Drug Administration label requires a longer minimum duration.
4. Four-Week Reassessment Rule: Continue a product beyond four weeks only if the wound area has decreased by at least 50%; otherwise, stop, reassess, and consider an alternative class.

4. Regulatory Tier Definitions:

- Tier 1 (Premarket Approval / Biologics License Application / Humanitarian Device Exemption): Food and Drug Administration-approved (Premarket Approval), licensed (Biologics License Application), or authorized (Humanitarian Device Exemption) products with labeled wound indications.
- Tier 2 (510(k)): Devices cleared for wound management indications (based on substantial equivalence).
- Tier 3 (Human Cells, Tissues, and Cellular and Tissue-based Products): Human cells/tissues regulated solely under section 361; no Food and Drug Administration wound-etiology approval.

Product and evidence summary table

Product	Pathway / Tier	Food and Drug Administration Identifier	Labeled Indication	Systematic Review	Key Guideline	Key Evidence (Author, Year)	Evidence Strength
Diabetic Foot Ulcers							

Apligraf (diabetic foot ulcer)	Premarket Approval / Tier 1	P950032/S 016 (May 22, 1998)	“Full-thickness neuropathic diabetic foot ulcers at least 3 weeks that	Santema, 2016	Hingorani, 2016	Veves, 2001	A
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			extend through the dermis, without tendon, muscle, capsule, or bone exposure; with standard care.”				
Dermagraft (diabetic foot ulcer)	Premarket Approval / Tier 1	P000036 (Sep 28, 2001)	“Full-thickness diabetic foot ulcers at least 6 weeks that extend through the dermis, without tendon, muscle, joint capsule, or bone exposure; in patients with adequate blood supply.”	Santema, 2016	Hingorani, 2016	Marston, 2003	B

Omnigraft (diabetic foot ulcer)	Premarket Approval / Tier 1	P900033/S 042 (Jan 7, 2016)	“Partial- and full-thickness neuropathic diabetic foot ulcers greater than 6 weeks, with no capsule, tendon, or	Sui, 2024	Hingorani, 2016	Driver, 2015	B
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			bone exposed, when used in conjunction with standard diabetic ulcer care.”				
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OASIS Matrix	510(k) / Tier 2	K061711 (Jul 19, 2006)	“Management of wounds including: partial and full-thickness wounds; pressure ulcers; venous ulcers; diabetic ulcers.” (device cleared for wound management, not etiologyspecific approval)	None found as of Nov 2025	Hingorani, 2016	None found as of Nov 2025	C
PriMatrix	510(k) / Tier 2	K083440 (Dec 12, 2008)	“Management of wounds... partial and full thickness... pressure, diabetic, and venous ulcers; seconddegree burns.”	None found as of Nov 2025	—	Kavros, 2014 (Prospective cohort)	C

			(devicecleared for wound manageme nt, not etiologyspecific approval)				
Kerecis (fish-skin)	510(k) / Tier 2	K132343 (Oct 23, 2013); K190528	“Treating partial- and full-thickness wounds, ulcers, and draining, surgical, and traumatic wounds.” (devicecleared for wound manageme nt, not diabetic foot ulcerspecific approval)	RuizMuñoz, 2024	—	Dardari, 2024	B
EpiFix	361 Human Cells, Tissues, and Cellular and Tissuebased Products / Tier 3	—	Not Food and Drug Administrati onapproved for wound indications.	Haugh, 2017	—	Zelen, 2013. Evidence base consists of small randomized controlled trials with sponsorship; heterogeneit y and risk-ofbias persist.	B

Grafix	361 Human Cells, Tissues,	—	Not Food and Drug Administration-	None found as of Nov 2025	—	Lavery, 2014. Evidence from small	B
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	and Cellular and Tissuebased Products / Tier 3		approved for wound indications.			randomized controlled trial; industry sponsorship noted.	
DermAC ELL	361 Human Cells, Tissues, and Cellular and Tissuebased Products / Tier 3	—	Not Food and Drug Administration approved for wound indications.	Sui, 2024	—	Walters, 2016. Evidence is largely nonrandomized.	C
Venous Leg Ulcers							

Apligraf (venous leg ulcer)	Premarket Approval / Tier 1	P950032 (May 22, 1998)	“Non-infected partial and full-thickness skin ulcers due to venous insufficiency greater than 1 month that extend through the dermis, without tendon, muscle, capsule, or bone exposure; with compression.”	Jones, 2013	O’Donnell, 2014	Falanga, 1998	A
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OASIS Matrix	510(k) / Tier 2	K061711 (Jul 19, 2006)	“Management of wounds including: partial and full-thickness wounds; pressure ulcers; venous ulcers; diabetic ulcers.” (device cleared for wound management, not etiology specific approval)	Jones, 2013	O’Donnell, 2014	Mostow, 2005	A
EpiFix	361 Human Cells, Tissues, and Cellular and Tissue-based Products / Tier 3	—	Not Food and Drug Administration approved for wound indications.	Haugh, 2017	—	Serena, 2014. Evidence base consists of small randomized controlled trials with sponsorship.	B

AmnioBand / Guardian	361 Human Cells, Tissues, and Cellular and Tissue-based Products / Tier 3	—	Not Food and Drug Administration approved for wound indications.	None found as of Nov 2025	—	Serena, 2022. Evidence from multicenter randomized controlled trial; industry sponsorship noted.	B
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Thermal Burns							
StrataGraft	Biologics License Application / Tier 1	STN 125730 (Jun 15, 2021)	“Treatment of adult patients with debrided thermal burns... intact dermal elements... for which surgical intervention is clinically indicated.”	None found as of Nov 2025	None found as of Nov 2025	Holmes, 2021	B

Integra Dermal Regenera tion Template	Premarket Approval / Tier 1	P900033 (Jan 7, 2016)	“Postexcisional treatment of life-threatening full-thickness or deep partialthickness thermal injuries... autograft not available or not desirable.”	None found as of Nov 2025	None found as of Nov 2025	Heimbach, 2003	C
TransCyte	Premarket Approval / Tier 1	P960007 (Mar 18, 1997)	“Temporary wound covering for surgically excised full-thickness and deep partial-thickness thermal	None found as of Nov 2025	None found as of Nov 2025	Kumar, 2004	B
			burns prior to autograft; and mid-dermal to indeterminate depth burns expected to heal without autografting .”				

RECELL Autologous Cell Harvesting Device	Premarket Approval / Tier 1	BP170122 (Sep 20, 2018)	“Treatment of thermal burn wounds and full- thickness skin defects; for direct application to acute partialthickness thermal burns in adults aged at least 18 years; or with meshed autograft for acute fullthickness thermal burns in pediatric and adult patients and fullthickness skin defects in patients aged at	Daneshi, 2025 (conference abstract only)	None found as of Nov 2025	Holmes, 2018	B
			least 15 years.”				

Epitel	Humanitarian Device Exemption / Tier 1	H990002 (Oct 25, 2007)	“Deep dermal or full thickness burns comprising ... at least 30% Total Body Surface Area.” Authorized under Humanitarian Device Exemption based on probable benefit, not demonstrated effectiveness.	None found as of Nov 2025	None found as of Nov 2025	Hickerson, 2019	B
Biobrane	510(k) / Tier 2	K242146 (Dec 17, 2024)	“Covering clean partial thickness burn wounds; Split thickness donor sites.” (device cleared for wound management, not etiologic specific approval)	Wasiak, 2013	None found as of Nov 2025	Kumar, 2004: pediatric partial-thickness burns; faster re-epithelialization vs silver sulfadiazine; comparator TransCyte arm reported.	B

Suprathel	510(k) / Tier 2	K090160 (May 20, 2009)	“Temporary coverage of noninfected skin defects, such as superficial wounds, under sterile conditions.” (device cleared for wound management, not etiologyspecific approval)	None found as of Nov 2025	None found as of Nov 2025	Hundeshagen, 2018	B
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Quick-reference and policy rules

Wound-to-product mapping table

Wound Characteristic	Preferred Product Class	Regulatory Tier Notes
Small/superficial diabetic foot ulcer (no exposure)	Bilayer living cell construct (e.g., Apligraf)	Tier 1; diabetic foot ulcer at least 3 weeks.
Moderate diabetic foot ulcer (through dermis, no exposure)	Cellular dermal scaffold (e.g., Dermagraft)	Tier 1; diabetic foot ulcer at least 6 weeks.
Partial–full thickness diabetic foot ulcer needing scaffold (no exposure)	Dermal regeneration template (e.g., Omnigraft)	Tier 1; diabetic foot ulcer at least 6 weeks.

When Tier 1 is unsuitable (diabetic foot ulcer/venous leg ulcer)	Xenogenic/acellular matrices (e.g., OASIS, Kerecis)	Tier 2; cleared for wound management.
Venous leg ulcer (with sustained compression)	Bilayer living cell construct (e.g., Apligraf)	Tier 1; venous leg ulcer greater than 1 month.
Partial-thickness burns	Biosynthetic temporary covers (e.g., Biobrane; Suprathel)	Tier 2; partialthickness/donor site coverage.
Deep partial-thickness burns needing surgery	Allogeneic cellular construct (StrataGraft)	Tier 1.
Full-thickness burns (bridge to autograft)	Temporary cover (TransCyte); dermal template (Integra)	Tier 1.
Extensive burns (at least 30% Total Body Surface Area)	Cultured autografts (Epicel)	Tier 1 (Humanitarian Device Exemption).
Autograft sparing/adjunct	Autologous cell harvesting (RECELL)	Tier 1.
Any ulcer with exposed tendon/bone/capsule	Not eligible for products above unless labeling explicitly permits.	Optimize surgical coverage first.

Chronicity thresholds table

Condition	Minimum Duration Before Advanced Therapy (per Food and Drug Administration Labeling)
Diabetic foot ulcer treated with Apligraf	at least 3 weeks

Diabetic foot ulcer treated with Dermagraft	at least 6 weeks
Diabetic foot ulcer treated with Omnigraft	at least 6 weeks
Venous leg ulcer treated with Apligraf	greater than 1 month (with compression)

Transcatheter Therapy for Severe Tricuspid Insufficiency

Clinical Policy ID: **CCP.1551**

Recent review date: **10/31/2025**

Next review date: **2/28/2027**

Policy contains: **Evogue; heart failure; TriClip; tricuspid insufficiency; tricuspid valve repair; tricuspid valve replacement.**

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case-by-case basis, by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

Transcatheter edge-to-edge repair and transcatheter tricuspid valve replacement procedures for severe tricuspid insufficiency (also called tricuspid regurgitation) are investigational/not clinically proven and, therefore, not medically necessary.

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- **Guideline-directed medical therapy**
- **Surgical tricuspid valve repair**
- **Surgical tricuspid valve replacement**

Background

Tricuspid insufficiency (or regurgitation) results from structural abnormalities of the tricuspid valve complex that cause incomplete valve closure and retrograde flow of blood from the right ventricle into the right atrium during systole. In U.S. adults, the incidence of tricuspid regurgitation ranges from 5% to 20%. Tricuspid regurgitation-related morbidity and mortality increase with severity (Mulla, 2024).

Tricuspid regurgitation is categorized as either primary, caused by intrinsic abnormalities in the tricuspid valve apparatus, or secondary, caused by right atrial or ventricular dilatation. A third category, tricuspid regurgitation related to a cardiac procedure such as endomyocardial biopsy or implantable electronic device, can develop if the device interferes with the tricuspid valve leaflets or subvalvular apparatus, or if right ventricular pacing leads to right ventricular remodeling (O’Gara, 2025).

A combination of structural, qualitative, semiquantitative, and quantitative measures using echocardiography is used to assess valvular morphology, severity of tricuspid regurgitation, and adjunctive cardiac features. Cardiac magnetic resonance and computed tomography may further define complex tissue structures. The severity of tricuspid regurgitation is commonly graded as mild (1+), moderate (2+), or severe (3+). More recently, severe disease may be further graded as massive or torrential. Guideline-directed diagnosis of severe tricuspid regurgitation is based on assessment of regurgitant jet area with vena contracta and presence of hepatic vein reverse flow. Severe (3+) classification is defined by a vena contracta diameter of at least 7 millimeters, effective regurgitant orifice area of at least 40 square millimeters, and/or a regurgitant volume of at least 45 milliliters per beat (Ambrosino, 2024).

Patients with severe tricuspid regurgitation usually present with signs or symptoms of right-sided heart failure. The prognostic impact of a tricuspid regurgitation diagnosis is well recognized, but the effect of its correction is less so. Treatment options are limited to guideline-directed medical therapy for symptom relief and surgery. Surgical intervention for isolated tricuspid regurgitation is relatively uncommon in the United States due to a perceived high in-hospital mortality rate of up to 10%, despite stringent selection criteria. Instead, surgery is performed typically for those who have another primary indication for surgery, such as concomitant mitral or aortic valvular disease, or to prevent later development of severe tricuspid regurgitation in patients with progressive tricuspid disease. Earlier referral and more effective techniques may improve patient outcomes (Ambrosino, 2024).

Transcatheter tricuspid valve interventions

Minimally invasive, transcatheter tricuspid valve interventions have emerged as potential options for tricuspid valve repair and replacement. The options for transcatheter repair are leaflet coaptation devices (tricuspid valve edge-to-edge repair) and annuloplasty. Transcatheter replacement options include orthotopic replacement of the tricuspid valve and heterotopic caval valve implantation (Ambrosino, 2024).

As of this writing, two transcatheter options have received regulatory approval for clinical use in the United States. The TriClip G4 transcatheter tricuspid valve repair system (Abbott Medical, St. Paul, Minnesota) is delivered via a transfemoral venous approach under transesophageal echocardiographic guidance. It uses a specialized clip to grasp and join together the edges of the leaking valve leaflets, which creates a stable double orifice. This device is indicated for improving quality of life and functional status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, who are at intermediate or greater risk for surgery and in whom transcatheter edge-to-edge valve repair is clinically appropriate and is expected to reduce tricuspid regurgitation severity to moderate or less, as determined by a multidisciplinary heart team. Regulatory approval is based on the results of the

TRILUMINATE Pivotal Trial (Kar, 2025; ClinicalTrials.gov identifier NCT03904147; U.S. Food and Drug Administration, 2024b).

The Edwards Evoque Tricuspid Valve Replacement System (Edwards Lifesciences LLC, Irvine, California) is made from bovine pericardial tissue, uses a transfemoral venous approach, and comes in three sizes. It replaces the native tricuspid heart valve without concomitant removal of the failed native valve. This device is indicated for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, in whom tricuspid valve replacement is deemed appropriate by a heart team. Regulatory approval was based on the safety and effectiveness results from the TRISCEND II pivotal trial (ClinicalTrials.gov identifier NCT04482062, U.S. Food and Drug Administration, 2024a).

Findings

Isolated severe tricuspid regurgitation is associated with high surgical risk and long-term mortality risk, and advances in medical and surgical management have not lowered mortality rates (Suc, 2025). Transcatheter options are recent additions that are safe and improve the severity of tricuspid regurgitation and health status in patients at high or prohibitive surgical risk, but evidence is lacking on mortality and heart failure hospitalization rates, efficacy in patients with mild or moderate tricuspid regurgitation, and long-term outcomes (Donal, 2025; Hahn, 2025; Sorajja, 2023). Current guidelines acknowledge the limited available evidence and provide mixed recommendations for clinical use outside of research protocols.

Guidelines

The current American College of Cardiology guideline on valvular heart disease acknowledges a growing interest in catheter-based therapies for tricuspid regurgitation but issued no recommendation (Otto, 2020).

In 2025, an American College of Cardiology writing committee summarized the most important developments for patients with severe tricuspid regurgitation, with emphasis on those with secondary tricuspid regurgitation in the chronic setting. Transcatheter interventions are in the early stages of new device development and testing in clinical trials. Most current trial data reflect a patient population with high or prohibitive surgical risk. Ongoing studies are comparing the effectiveness of transcatheter options to optimal medical therapy; comparisons to isolated tricuspid valve surgery or to other transcatheter options have not been conducted. The writing committee recommends counseling patients on expected benefits and risks with both surgical and available transcatheter interventions within a multidisciplinary team consensus and shared decision-making (O’Gara, 2025).

The European Society of Cardiology and the European Association for Cardio-Thoracic Surgery joint guideline on the management of valvular heart disease addressed all transcatheter tricuspid valve options available in the European Union, including TriClip and Evoque. The guideline states transcatheter tricuspid valve treatment should be considered to improve quality of life and right ventricular remodeling in high-risk patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, and in the absence of severe right ventricular dysfunction or pre-capillary pulmonary hypertension (Class IIa recommendation; Level of evidence A based on data derived from randomized controlled trials or meta-analyses) (Praz, 2025).

The National Institute for Health and Care Excellence (2022) states transcatheter tricuspid valve leaflet repair should only be used with special arrangements for clinical governance, consent, and audit or research. For individuals with severe and symptomatic tricuspid regurgitation, evidence on efficacy is

limited in quantity and quality, and there are serious but well-recognized complications. For individuals with mild or moderate tricuspid regurgitation, evidence on the safety and efficacy is of inadequate quantity and quality.

Evidence review

Data from three randomized controlled trials demonstrate the safety and efficacy of transcatheter tricuspid valve repair (TriClip) and replacement (Evoque) procedures in reducing the severity of tricuspid regurgitation in more than 80% of cases where anatomical suitability was confirmed. These results and improvement in health status were sustained up to one year for Evoque and up to two years for TriClip. The effects of transcatheter interventions on rates of heart failure hospitalization and mortality may be realized with longer follow up, as evidence for TriClip suggests.

Transcatheter edge-to-edge repair is the most extensively studied transcatheter technique for severe tricuspid regurgitation. Compared to TriClip, Evoque is associated with more procedural complications but a lower rate of residual tricuspid regurgitation. It appears to be most suitable for patients who have anatomy that precludes repair, and it has the ability to treat a wider range of tricuspid regurgitation pathologies.

Transcatheter tricuspid valve edge-to-edge repair (TriClip)

The evidence for the TriClip procedure consists of results from the TRILUMINATE Pivotal trial carried out in the United States (n = 350; Jorde, 2024; Kar, 2025; Naik, 2025; Sorajja, 2023) and from the TRI.Fr randomized controlled trial in Europe (n = 300; Donal, 2025). Both trials compared the safety and efficacy of optimized medical therapy with and without TriClip for treating severe, symptomatic, isolated tricuspid regurgitation. Both trials reported outcomes at 12 months. TRILUMINATE also reported full two-year follow-up data (Kar, 2025) and three-year follow-up data from a cohort of TriClip recipients (Nickenig, 2024).

The main eligibility criteria for inclusion in both of these trials were New York Heart Association class II to IV heart failure; on guideline-directed medical therapy and stable for at least 30 days; free from other cardiovascular conditions requiring intervention; and considered intermediate-to-high risk for surgery. In general, participants with highly advanced disease (e.g., severe kidney failure, liver failure, advanced cardiorenal syndrome, or pulmonary artery systolic pressure > 60 millimeters of mercury) were excluded. The mean age of participants was 78 years, and a slight majority were women. Participants had significantly impaired quality of life at baseline, and a high proportion experienced heart failure hospitalizations in the previous year (Donal, 2025; Sorajja, 2023).

TriClip safety

Transcatheter tricuspid valve edge-to-edge repair using TriClip is a safe procedure in experienced hands. TriClip was successfully implanted in at least 97% of participants. TriClip was associated with low rates of periprocedural adverse events, which were comparable to the control arms. At 12 months, rates of major cardiovascular events, deaths, and hospitalizations were similar between study arms. Single-leaflet device attachments occurred in 5.2% in the TRI.Fr trial and 7.0% in the TRILUMINATE trial (Donal, 2025; Sorajja, 2023).

In the TRI.Fr trial, three recipients of TriClip required tricuspid valve surgery, five required a cardiac electronic rhythm device, and nine experienced a major bleed. These results did not differ significantly from the control group (Donal, 2025). In the TRILUMINATE trial, five TriClip recipients and five in the control group required a cardiac electronic rhythm device (Sorajja, 2023).

TriClip efficacy

The TRILUMINATE and TRI.Fr trials used composite clinical endpoints at 12 months as their primary outcome measures. The composite endpoints differed in composition but included elements of objective adverse cardiovascular event data and patient-reported outcome measures (Donal, 2025; Sorajja, 2023).

At year one, the results of the primary endpoint favored the TriClip arm, driven by the magnitude of improvement in patient-reported outcome measures, including quality of life, rather than by changes in the rates of cardiovascular hospitalization or cardiovascular death. Significantly more TriClip recipients experienced a reduction in the severity of tricuspid regurgitation, from severe or greater to moderate or less, than those on optimized medical therapy alone. These results suggest a correlation between quality-of-life improvement and reduction in tricuspid regurgitation up to one year following the procedure. The trials reached different conclusions regarding the impact of TriClip on the six-minute walk test distance (Donal, 2025; Sorajja, 2023).

A separate analysis of 98 participants with transvalvular cardiac implantable electronic devices at baseline found TriClip repair was safe and effective and did not affect device function up to one year (Naik, 2025). Jorde (2024) observed potential benefits for TriClip repair in improving end organ renal and liver function, but additional research is needed to assess whether the statistically significant improvements are clinically meaningful and reduce mortality or heart failure hospitalization.

At year two, results of the TRILUMINATE trial showed sustained benefits of TriClip repair versus controls in terms of improved tricuspid regurgitation, health status, and comparable adverse event rates. Notably, 59% of the control participants crossed over to the TriClip group before the two-year follow-up. From year one to year two, the TriClip group showed a significantly greater reduction in the rate of heart failure hospitalization and freedom from all-cause mortality, tricuspid valve surgery, and tricuspid valve intervention compared with medical therapy. These findings were driven by the crossover of controls to the TriClip group, who were more symptomatic and had more severe tricuspid regurgitation, higher hospitalization rates, and worsened functional score than those who remained in the control group. Rates of all-cause mortality and tricuspid valve surgery remained similar between groups (Kar, 2025).

At year three, in a subset of 98 TRILUMINATE TriClip recipients, major adverse events included cardiovascular mortality (n = 18), myocardial infarction (n = 1), stroke (n = 4), and new onset of renal failure (n = 8). Benefits in reduced tricuspid regurgitation, favorable remodeling of the right heart, and improved heart failure symptoms were maintained. There was a 75% reduction in heart failure hospitalizations, from 0.56 events/patient-year in year one to 0.14 events/patient-year in year three ($P < .0001$). Those who achieved a reduction in tricuspid regurgitation from severe or greater to moderate or less at 30 days were less likely to experience heart failure hospitalization or death by year three compared with those who maintained severe or greater tricuspid regurgitation at 30 days (30.7% vs. 50.7%, hazard ratio = 0.48, 95% confidence interval 0.25 to 0.93, $P = .026$). Quality of life, measured by the Kansas City Cardiomyopathy Questionnaire score, initially improved in year one, but declined at year three, yet still maintained a 10-point improvement over baseline (Nickenig, 2024).

Transcatheter tricuspid valve replacement (Evoque)

The evidence for transcatheter tricuspid valve replacement using Evoque consists of results from the TRISCEND II pivotal randomized controlled trial (Arnold, 2025; Hahn, 2025). Eligibility criteria included participants at least 18 years of age with severe, massive, or torrential tricuspid regurgitation, who were eligible for valve replacement, and had either signs or symptoms of tricuspid regurgitation or a recent hospitalization for associated heart failure despite medical therapy. The vast majority of enrollees were white women with a mean age of 79 years. There was a high prevalence of hypertension, atrial fibrillation, left ventricular ejection fraction of more than 50%, and substantially

impaired health status at baseline. Participants also had a high prevalence of renal insufficiency and history of bleeding (Hahn, 2025).

Participants were randomized to the valve-replacement group (n = 267) or medical therapy alone (n = 133). The hierarchical composite primary outcome was death from any cause, implantation of a right ventricular assist device or heart transplantation, subsequent tricuspid-valve intervention, heart failure hospitalization, an improvement of at least 10 points in the score on the Kansas City Cardiomyopathy Questionnaire overall summary, an improvement of at least one New York Heart Association functional class, and an improvement of at least 30 meters on the six-minute walk test distance. Investigators used the win ratio to analyze the composite endpoint, which prioritizes each element based on clinical importance in terms of the proportion of successful outcomes compared to unsuccessful ones (Hahn, 2025).

Evoque safety

Most adverse clinical events occurred peri-procedurally, driven primarily by severe bleeding (10.4% in the valve replacement group vs. 1.5% in controls, $P = .003$) and conduction disorders leading to new pacemaker implantation (15.8% vs. 0%, $P < .001$).

Evoque efficacy

At 30 days, the rates of death from any cause ($P = .87$) and death from cardiovascular causes ($P = .85$) were similar between groups. At year one, the primary composite endpoint favored valve replacement over medical therapy (win ratio 2.02, 95% confidence interval 1.56 to 2.62, $P < .001$), driven primarily by improvements in symptoms and quality of life. Echocardiographic outcomes favored the valv replacement group, in whom tricuspid regurgitation was decreased to a mild degree or less in 95.2% compared with 2.3% of those in the control group. Authors observed improvements in right ventricular reverse remodeling and in markers of liver congestion (Hahn, 2025).

Adding transcatheter valve replacement resulted in substantial improvement in participants' symptoms, function, and quality of life over medical therapy alone. The magnitude of the health status benefit was directly related to the baseline severity of tricuspid regurgitation. Moderate benefits were evident 30 days after the procedure, continued to improve through the first six months, and were maintained through year one (Arnold, 2025).

References

On 9/23/2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "tricuspid valve insufficiency" (MeSH), "tricuspid valve insufficiency," "tricuspid valve regurgitation," "TriClip," and "EVOQUE." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

11/3/2025 initial review date and clinical policy effective date: TBD



ZOLL Heart Failure Management System

Clinical Policy ID: **CCP.1547**

Recent review date: **7/31/2025**

Next review date: **11/30/2026**

Policy contains: **Heart failure; pulmonary edema; remote monitoring; uCor; ZOLL Heart Failure Management System.**

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies, along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation, are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

The ZOLL® Heart Failure Management System (ZOLL Manufacturing Corporation, San Jose, California) is investigational/not clinically proven and, therefore, not medically necessary.

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Guideline-directed care for heart failure.

Background

Heart failure, also called congestive heart failure, occurs when the heart cannot pump enough blood and oxygen to support other body organs. This can result from any structural or functional impairment of ventricular filling or pumping. Heart failure is a leading cause of morbidity and mortality and a substantial burden to health care systems. Racial and ethnic disparities in heart failure-related mortality persist, with non-Hispanic Black patients having the highest death rate per capita (Heidenreich, 2022).

Heart failure is defined clinically in several ways. The American College of Cardiology/American Heart Association's four stages emphasize the development and progression of disease in which advanced stages are associated with reduced survival. The New York Heart Association Classification characterizes patient symptoms and functional capacity, is an independent predictor of mortality, and is used to determine treatment eligibility. Left ventricular ejection fraction reflects differing prognosis and response to treatments and has been used to determine clinical trial eligibility (Heidenreich, 2022).

In the United States, an estimated 6.7 million people live with heart failure. Its prevalence is projected to increase further, affecting more than eight million adults age 18 years and older by 2030 (Martin, 2025). Initial hospitalizations and rehospitalizations (30- and 90-day) account for the largest component of direct medical costs attributed to heart failure diagnoses (Osenenko, 2022).

Current methods to reduce decompensation leading to heart failure hospitalizations include frequent weight monitoring, blood pressure measurements, Holter monitoring, and telehealth platforms for structured assessment of symptoms. However, these methods often reflect later changes in decompensation and are time-consuming and resource-intensive. Remote monitoring devices, broadly categorized as implantable or less invasive wearable options, have been developed to detect impending signs of heart failure decompensation and reduce heart failure hospitalization (Kobe, 2023).

The ZOLL Heart Failure Management System, formerly the μ Cor Heart Failure and Arrhythmia Management System, is a wearable, patch-based sensor that uses radiofrequency technology to measure the Thoracic Fluid Index for early detection of changes in pulmonary fluid levels. It is intended to continuously record, store, and transmit thoracic fluid data along with heart rate, respiratory rate, activity, posture, and heart rhythm. The U.S. Food and Drug Administration issued 510(k) premarket approval intended for patients who are 21 years of age or older who require either monitoring for the detection of non-lethal cardiac arrhythmia (including, but not limited to, atrial fibrillation, atrial flutter, ventricular ectopy, and bradyarrhythmia) or monitoring fluid management (U.S. Food and Drug Administration, 2018).

Findings

Guidelines

The 2022 American Heart Association/American College of Cardiology/Heart Failure Society of America guideline for the management of heart failure does not address the use of non-invasive wireless technology to monitor pulmonary fluid levels as an early indicator for heart failure decompensation or arrhythmia detection (Heidenreich, 2022).

A scientific statement by the Heart Failure Society of America lists the ZOLL Heart Failure Management System (herein called "ZOLL") among a number of device-based therapies under investigation that may address an unmet need in the future (Estep, 2024).

Evidence review

The evidence of the effectiveness of the ZOLL device to track pulmonary edema is limited to two validation studies and one concurrent-control trial. While there is an unmet need for early detection of heart failure decompensation to avoid heart failure hospitalization, there is insufficient evidence documenting long-term outcomes and who would most benefit from this technology (e.g., those with or without associated pulmonary edema or on diuretic therapy).

Early validation studies analyzed the ability of the μ Cor Heart Failure and Arrhythmia Management

System to measure a patient's fluid status. In 20 participants with end-stage kidney disease with or without heart failure, 17 exhibited very strong or strong correlations (Pearson's correlation coefficient $r \geq 0.7$) between μ Cor thoracic fluid measurement and total body fluid removal during dialysis (Connaire, 2020; ClinicalTrials.gov identifier NCT03072732). In another trial of 66 inpatients recently admitted with acute heart failure (predominantly New York Heart Association functional class III to IV) and 54 healthy or stable controls, the diagnostic performances of μ Cor and computed tomography were similar: sensitivity 70% versus 86%; specificity 82% versus 83%; positive predictive value 82% versus 86%; negative predictive value 69% versus 83%, respectively, and correlation was strong ($r = 0.7$, $P < .001$) (Wheatley-Guy, 2020).

The evidence of clinical benefit is limited to one manufacturer-sponsored, multicenter, prospective, concurrent-control trial (Boehmer, 2024). The control arm ($n = 245$) was labeled Benefits of Microcor in Ambulatory Decompensated Heart Failure (BMAD-HF), ClinicalTrials.gov identifier NCT03476187), and the intervention arm ($n = 249$) was labeled Benefits of Microcor in Ambulatory Decompensated Heart Failure (BMAD-TX; ClinicalTrials.gov identifier NCT04096040). The study enrolled participants who had a recent hospitalization within 10 days for heart failure and a heart failure event within the previous six months. Participants in the intervention arm wore the ZOLL patch continuously for 90 days. Using intention-to-treat analysis, the primary endpoint was time to first heart failure hospitalization. Secondary endpoints included a composite heart failure-related events (emergency department visits, hospitalizations, and death) and quality of life as measured with the 12-item Kansas City Cardiomyopathy Questionnaire.

Compared with the control arm, participants using ZOLL lung fluid monitoring had a 37% reduction in heart failure hospitalization (hazard ratio = 0.63, $P = .03$, absolute reduction = 7%), a 38% reduction in the composite outcome of heart failure events ($P = .02$, absolute reduction = 9%), and clinically meaningful improvement in quality of life (12 points higher, $P = .004$). Study limitations included a short follow-up period, lack of randomization, a non-blinded intervention arm, and small but significant baseline differences in the use of angiotensin receptor–neprilysin and sodium glucose cotransporter 2 inhibitors between arms. The effects of COVID-19 on remote management considerations, presence of pulmonary congestion at enrollment, and need for diuretic agents are unclear (Boehmer, 2024).

Extrapolating from the above trial data, Bosworth Smith (2025) estimated ZOLL's cost-effectiveness over a five-year time horizon in the United States context. Compared to the standard of care, an estimated \$6,723 reduction in care costs and fewer hospital readmissions (mean, 1.075 versus 1.201 per patient) were projected at five years with ZOLL monitoring. However, there is considerable uncertainty in the model inputs after 90 days, and long-term data are needed to confirm analytical trends.

References

On July 10, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Monitoring, physiologic” (MeSH), “Heart failure” (MeSH), “remote sensing technology,” “ μ Cor,” “ZOLL,” and “heart failure management system.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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