# Closing the gap: Expanding Medicare Part D coverage for over-the-counter nutritional supplements to improve wound healing outcomes

**Background:** Chronic wounds impose a substantial clinical and economic burden in Medicare in the US, as well as globally. Malnutrition is common and can delay healing; yet Medicare Part D excludes most over-the-counter nutrition products.

**Aims:** To evaluate policy options to expand Part D access to clinically indicated OTC nutrition supports for adults with chronic wounds.

**Methods:** A policy analysis using Bardach's Eightfold Path generated six options and applied five criteria (effectiveness, feasibility, cost impact, equity, and stakeholder support) informed by source-article evidence (randomised trials and recent reviews) and federal policy and guidance documents.

**Results:** The CMS-approved supplement formulary and a Center for Medicare and Medicaid Innovation pilot scored highest overall. Evidence supports targeted oral nutritional supplements and selected micronutrients for malnourished/high-risk populations, with mixed results for routine use.

**Conclusion:** A sequenced approach (pilot then scale) covering clinically indicated oral nutritional supplements and micronutrients with dietitian involvement and safeguards (screening/biomarkers, utilisation controls) is feasible under existing CMS authorities, promotes equity, and enables real-world evaluation before broader adoption.

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**Key words**
- Medicare
- Nutrition
- Policy
- Supplements
- Wound healing

Chronic wounds remain a major public health and economic challenge, affecting one in six Medicare beneficiaries in the US and driving substantial spending; global costs are also high (Nussbaum et al, 2018; Sen, 2025).

Malnutrition and suboptimal intake are prevalent among adults with chronic wounds and mechanistically impair inflammatory resolution, collagen synthesis, angiogenesis and core processes of repair (Grada and Phillips, 2022; Hajj et al, 2024).

Evidence shows that targeted oral nutritional supplements (ONS) can improve healing in selected high-risk groups. In malnourished adults with pressure injuries, a high-protein formula enriched with arginine, zinc, and antioxidants achieved a significantly greater ulcer-area reduction than an isocaloric/isoprotein control over 8 weeks (Cereda et al, 2015).

In diabetic foot ulcers (DFU), a multicentre randomised trial of arginine + glutamine + β-hydroxy-β-methylbutyrate found no overall difference in complete closure at 16 weeks, but patients with low albumin and/or reduced perfusion (ankle–brachial pressure index <1.0) had significantly higher healing rates with supplementation, suggesting benefit when clinical indication is present (Armstrong et al, 2014).

In the last decade, systematic and narrative reviews have reported positive effects most consistently with multi-nutrient ONS (high-protein with antioxidant micronutrients) in malnourished or elderly populations, while noting heterogeneity that argues against blanket use for all wounds (Santo et al, 2024; Seth et al, 2024).

Despite this rationale for targeted supplementation, Medicare Part D excludes most OTC products by rule, creating affordability barriers and perpetuating inequities (Seth et al, 2024).

Therefore, we applied Bardach's Eightfold Path to evaluate options that responsibly expand Part D access to clinically indicated OTC nutrition support for adults with chronic wounds, balancing effectiveness, feasibility, cost impact, equity and stakeholder support

(Bardach and Patashnik, 2019; Centers for Medicare & Medicaid Services [CMS], 2026).

## Methods

### Author team

The team comprises a clinician-researcher and nurse practitioner with wound care and clinical trials experience (KD), a professor of community and global health and registered dietitian (SMB), and a nursing science professor and health services researcher (JO). The team conducted the analysis and adjudicated scoring by consensus.

### Analytic approach (Bardach's Eightfold Path)

We followed Bardach and Patashnik's eight steps: (1) define the problem; (2) assemble evidence; (3) construct alternatives; (4) select criteria; (5) project outcomes; (6) confront tradeoffs; (7) decide; and (8) tell the story (Bardach and Patashnik, 2019).

Evidence inputs for effectiveness emphasised source articles (randomised trials and recent systematic/narrative reviews), while feasibility, cost, equity and stakeholder support drew on CMS regulations/rulemaking and oversight documents (Armstrong et al, 2014; Molnar et al, 2014; Cereda et al, 2015; Grada and Phillips, 2022; CMS, 2023; International Working Group on the Diabetic Foot [IWGDF], 2023; Santo et al, 2024; Seth et al, 2024; Department of Health and Human Services [HHS], 2026).

### Policy alternatives

We evaluated six options: (1) expand Part D to cover select OTC supplements; (2) a CMS-approved supplement formulary under enhanced alternative coverage; (3) a CMMI pilot; (4) incentivise Medicare Advantage (MA) plans to expand OTC benefits when clinically indicated; (5) reclassify certain products as medical foods; and (6) status quo.

Feasibility judgments referenced Part D statutory/regulatory constraints and recent CMS policy activity (Seth et al, 2024; HHS, 2026; CMS, 2023).

### Evaluation criteria and operational definitions

**Effectiveness:** Likely clinical impact (healing, time-to-closure, infection, amputation), weighted toward randomised evidence and systematic reviews; subgroup signals (e.g. malnutrition/ischaemia) noted (CMS, 2023; Seth et al, 2024; HHS, 2026).

**Feasibility:** Fit with existing Part D authorities, formulary governance, administrative complexity, and implementation risk (CMS, 2023; Seth et al, 2024; HHS, 2026).

**Cost impact:** Directional net budget impact (supplement spend minus potential offsets from improved outcomes), with uncertainty stated transparently.

**Equity:** Expected access effects for groups facing disadvantage (e.g. malnutrition risk, high neighborhood deprivation, rurality) given the current OTC exclusion (Seth et al, 2024).

**Stakeholder support:** Anticipated positions of CMS, MA plans, clinicians, beneficiaries, advocacy groups, and manufacturers; we considered emerging oversight/reporting of MA OTC benefits (CMS, 2023 HHS, 2026).

**Definition of "supplements" (scope for this policy):** For this analysis, OTC supplements include: (1) oral nutritional supplements (ONS) (high-protein and disease-specific formulas) used when clinically indicated (e.g. positive nutrition screen, Global Leadership Initiative on Malnutrition [GLIM] diagnosis, or biomarker deficiency); and (2) selected micronutrients (e.g. vitamin C, vitamin D, zinc) used to treat documented deficiency or high-risk biological states relevant to wound physiology. Evidence favours targeted rather than routine use for all wound patients (Armstrong et al, 2014; Molnar et al, 2014; Cereda et al, 2015; Grada and Phillips, 2022; Santo et al, 2024).

**Guardrails informing projections:** We incorporated IWGDF (2023) guidance cautioning against routine supplements to "enhance healing" in DFU absent indication, supporting eligibility criteria and stewardship if coverage expands.

### Policy assumptions and scope

This analysis assumes that nutritional supplementation is most effective when used to address documented malnutrition or deficiency and when integrated with guideline-concordant wound care. It does not assume benefit from indiscriminate supplementation in all patients with chronic wounds, particularly those with diabetic foot ulcers, consistent with current clinical guidance. The analysis further assumes that coverage expansion would be implemented with utilisation of safeguards, including nutrition screening, documentation of clinical indication, time-limited authorisation, and reassessment of need. Cost projections assume partial offset through reductions in wound-related complications rather than immediate net savings. Finally, this analysis focuses on Medicare beneficiaries in outpatient wound care settings; findings may not generalise to acute inpatient populations or non-Medicare payers.

## Results

### Scoring rationale

We anchored each 1–5 score to rubric definitions (below). For example, the

CMS-approved supplement formulary scored 5 (feasibility) due to alignment with Part D enhanced alternative coverage and formulary governance; 4 (effectiveness) reflecting supportive evidence in malnourished/high-risk groups with heterogeneity overall; 3 (cost) acknowledging near-term spend with potential offsets; 5 (equity) by reducing plan-level variability; and 4 (stakeholder support) anticipating beneficiary/clinician advocacy with manageable payer concerns under guardrails (Armstrong et al, 2014; Cereda et al, 2015; Grada and Phillips, 2022; CMS, 2023; Santo et al, 2024; Seth et al, 2024; HHS, 2026). By contrast, status quo scored 1 (effectiveness) and 1 (equity) (persistent access barriers) but 5 (feasibility) and 5 (stakeholder support) (administrative simplicity), illustrating tradeoffs motivating our recommendation (Seth et al, 2024).

Stakeholder influence was assessed qualitatively using policy documents and published literature to examine feasibility and equity implications. **Table 1** outlines key stakeholders, their roles, and sources of influence.

Policy alternatives were then scored across five criteria: effectiveness, feasibility, cost impact, equity, and stakeholder support. **Table 2** summarises the comparative scoring for all six alternatives. As shown, the CMS-approved supplement formulary and CMS Innovation Center pilot program achieved the highest total scores (21 points each), indicating strong feasibility and equity.

To illustrate these findings visually, **Figure 1** presents a color-coded bar graph ranking policy alternatives by total score, making comparative differences easier to interpret

**Scoring anchors**

**Effectiveness (1–5):** 1 = no benefit/harms likely; 3 = mixed/uncertain; 5 = consistent benefit in indicated populations supported by randomised controlled trials and reviews (Armstrong et al, 2014; Molnar et al, 2014;

**Table 1. Stakeholder roles and sources of influence**

| Stakeholder | Role | Source of influence |
|---|---|---|
| CMS | Policy authority | Regulatory power, budget control |
| Medicare beneficiaries | End users | Voting power, advocacy |
| Healthcare providers | Clinical advocates | Expertise, professional networks |
| Supplement manufacturers | Industry | Financial resources, lobbying |
| Advocacy groups (e.g. wound care associations) | Equity champions | Public campaigns, partnerships |
| Medicare advantage plans | Plan administrators | Market leverage, flexibility in benefits |

**Table 2. Comparative scoring of policy alternatives**

| # | Policy alternative | Effectiveness | Feasibility | Cost impact | Equity | Stakeholder support | Total |
|---|---|---|---|---|---|---|---|
| 1 | Expand Part D to cover select OTC supplements | 5 🟢 | 3 🟡 | 2 🔴 | 5 🟢 | 3 🟡 | 18 |
| 2 | CMS-approved supplement formulary | 4 🟢 | 5 🟢 | 3 🟡 | 5 🟢 | 4 🟢 | 21 |
| 3 | CMS Innovation Center pilot program | 3 🟡 | 5 🟢 | 4 🟢 | 4 🟢 | 5 🟢 | 21 |
| 4 | Incentivise MA plans to expand OTC benefits | 3 🟡 | 5 🟢 | 4 🟢 | 3 🟡 | 4 🟢 | 19 |
| 5 | Reclassify supplements as medical foods | 4 🟢 | 2 🔴 | 3 🟡 | 5 🟢 | 3 🟡 | 17 |
| 6 | No change/status quo | 1 🔴 | 5 🟢 | 5 🟢 | 1 🔴 | 5 🟢 | 17 |

Cereda et al, 2015; Grada and Phillips, 2022; Santo et al, 2024).

**Feasibility:** 1 = likely requires new statute; 3 = moderate rulemaking/administrative lift; 5 = implementable under existing CMS authorities/formulary processes (CMS, 2023; Seth et al, 2024; HHS, 2026).

**Cost impact:** 1 = net increase with low offset potential; 3 = uncertain/offsets plausible; 5 = strong offset potential (framework).

**Equity:** 1 = maintains access barriers; 3 = partial/plan variability; 5 = materially improves access for indicated groups nationally (Seth et al, 2024).

**Stakeholder support:** 1 = broad opposition; 3 = mixed; 5 = likely coalition (beneficiaries, clinicians) and manageable payer/regulator concerns with guardrails (CMS, 2023).

## Discussion

This analysis indicates that targeted Medicare coverage for clinically indicated ONS and selected micronutrients could improve outcomes for malnourished or otherwise high-risk adults with chronic wounds, while avoiding indiscriminate use that guidelines and mixed trial results do not support. The pressure-injury randomised controlled trial evidence (arginine–zinc–antioxidant ONS) and DFU subgroup effects (albumin ≤4.0 g/dl and/or ischaemia) exemplify contexts in which supplementation may confer clinically meaningful benefit alongside guideline-concordant wound care (Armstrong et al, 2014; Molnar et al, 2014; Cereda et al, 2015; IWGDF, 2023).

### Implementation and equity considerations

From an implementation standpoint, a CMS-approved supplement formulary or time-limited CMMI pilot are viable pathways. Although Part D currently excludes OTCs, CMS maintains mechanisms (enhanced alternative benefits, formulary governance), and MA OTC benefits are under increasing oversight, together providing administrative precedent to test and scale a tightly specified benefit (CMS, 2023 Seth et al, 2024; HHS, 2026).

Equity considerations are central: under the OTC exclusion, low-income beneficiaries and those in disadvantaged neighbourhoods face disproportionate barriers to indicated supplements. A national formulary with clear eligibility criteria (e.g. positive nutrition screen or GLIM diagnosis, dietitian referral, documented deficiency or biomarker abnormality) and utilisation safeguards (e.g. prior authorisation tied to screening results; time-limited coverage with reassessment) could standardise access and mitigate overuse (Seth et al, 2024).

Under existing authority, a CMS approved supplement formulary could be implemented as an enhanced alternative Part D benefit, with coverage limited to clinically indicated

**Figure 1.** Policy alternatives ranked by total score

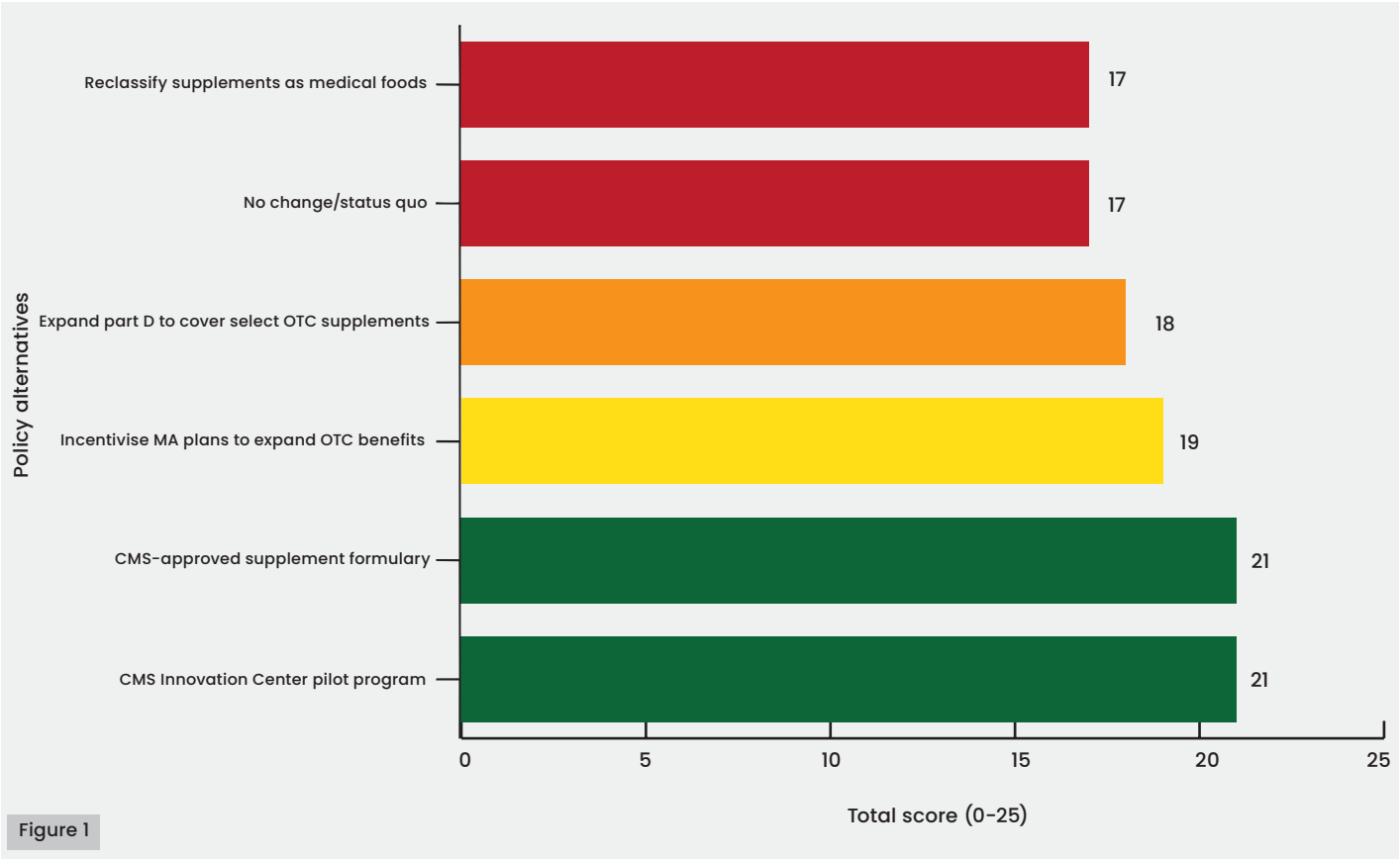


Figure 1

oral nutritional supplements and select micronutrients included on plan formularies. Products would be distinguished from excluded OTC items through formulary governance, documentation of medical necessity, and utilisation controls, consistent with CMS precedent for formulary exceptions and recent oversight of supplemental nutrition benefits.

Operationalising a CMS-approved supplement formulary or CMMI pilot would require clear eligibility criteria, standardised documentation, and alignment with existing clinical workflows. Eligibility could be triggered by validated nutrition screening tools, a GLIM malnutrition diagnosis or documented micronutrient deficiency, with referral to a registered dietitian to guide product selection and duration.

Coverage could be time-limited (e.g. 8–16 weeks) with reassessment tied to wound progress and nutritional status. Integration with electronic health records would enable monitoring of utilisation, outcomes, and equity impacts while minimising administrative burden. Importantly, positioning supplementation as an adjunct to (not a substitute for) standard wound care and offloading would reduce the risk of inappropriate reliance on nutrition products alone.

**Risks, limitations, and policy evaluation**

Concerns about overuse, inappropriate utilisation, or substitution of supplements for standard wound care are valid. However, these risks are mitigated when coverage is tied to documented clinical indication, dietitian oversight, and reassessment of need. Similar utilisation controls are routinely applied to other Medicare benefits and could be adapted for nutritional support. Importantly, maintaining the status quo also carries risk – namely, delayed healing and avoidable complications among patients who cannot afford recommended supplementation.

In the short term, targeted coverage of clinically indicated nutritional supplements would likely increase Part D spending due to added product costs and associated care coordination. However, these expenditures may be partially offset over time through downstream reductions in wound related complications, including infections, hospitalisations, emergency department visits, and lower extremity amputations, which are among the costliest sequelae of chronic wounds (Nussbaum et al, 2018; Sen, 2025).

Since the magnitude and timing of these offsets are uncertain, a time-limited pilot or staged formulary implementation would allow CMS to evaluate net budget impact alongside clinical and equity outcomes.

Limitations include heterogeneity in formulations and outcomes across trials, risk of indication creep without guardrails, and uncertainty around net budget impact. These support a pilot-first approach with predefined evaluation metrics (healing/closure, infection, amputation, hospitalisations, cost/utilisation, and equity; stratified by malnutrition status and social risk; IWGDF, 2023; Santo et al, 2024).

Evaluation of a CMMI pilot or CMS-approved formulary should include clinical, utilisation, cost, and equity endpoints. Core outcomes may include time to wound closure, infection rates, lower-extremity amputation, wound-related hospitalisations, and total cost of care. Nutritional outcomes (e.g. improvement in malnutrition status or correction of micronutrient deficiencies) would help link supplementation to biological plausibility. Equity-focused analyses should assess differential access and outcomes by socioeconomic disadvantage, rurality, and dual-eligibility status. These measures would enable CMS to determine whether targeted nutritional coverage improves outcomes without unintended overuse or inequitable implementation.

Although this analysis focuses on US Medicare policy, the underlying challenge of limited access to clinically indicated nutritional support is common across health systems, making these findings relevant to international efforts to improve chronic wound outcomes.

For clinicians managing chronic wounds, the lack of coverage for clinically indicated nutritional support often creates a gap between evidence-based recommendations and what patients can realistically access. When supplements are not covered, clinicians may rely on suboptimal dietary advice alone or face difficult choices when patients cannot afford recommended products. A targeted Medicare coverage pathway (anchored to nutrition screening, dietitian involvement, and time-limited use) would better align clinical decision-making with best practices while preserving stewardship. Importantly, such an approach supports interdisciplinary care by reinforcing the role of registered dietitians within wound teams.

## Conclusion

We recommend a sequenced approach: launching a CMMI pilot or CMS-approved supplement formulary that covers clinically indicated ONS/micronutrients for chronic wound patients only when eligibility criteria are met (nutrition screening/GLIM diagnosis

or documented deficiency; registered dietitian referral; integration with standard wound care). This approach aligns with the evidence base (benefits in malnourished/high-risk populations; mixed results otherwise), leverages existing CMS authorities, advances equity, and allows rigorous real-world evaluation of costs and outcomes before national scale-up. For policymakers, this analysis highlights a feasible pathway to address a well-documented clinical gap using existing CMS authorities while preserving stewardship and enabling rigorous evaluation before national scale-up.

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