FEMTEC

DRAFT TECHNICAL REPORT

Quality, Safety, Efficacy and Cost-effectiveness of Hydrotherapy and Balneotherapy

Critical review of recent evidence, 2021–2026

Introduction

Purpose. This report critically reviews recent evidence relevant to the quality, safety, efficacy and cost-effectiveness of hydrotherapy and balneotherapy, with emphasis on literature published during 2021–2026.

Recent evidence supports a clinically relevant signal of benefit in selected indications, particularly musculoskeletal conditions such as osteoarthritis, chronic low back pain and fibromyalgia. However, the certainty of the evidence is not uniform. A comprehensive 2025 meta-analysis of 42 randomized balneotherapy trials in rheumatology found favourable pooled estimates for pain and quality of life, but rated the certainty of those effects as very low because of risk of bias, inconsistency and suspected publication bias [3]. Condition-specific reviews are often more favourable, yet still identify substantial heterogeneity in interventions, comparators, outcome measures and study quality [4–9].

Safety. Available trial evidence does not demonstrate a consistent excess of adverse events with medically supervised hydrotherapy or balneotherapy, but safety reporting is incomplete. In the 2025 rheumatology meta-analysis, only 5 of 42 trials contributed data on adverse events and only 2 trials on serious adverse events; estimates were inconclusive [3]. Therefore, an acceptable short-term tolerability profile should not be interpreted as proof of universal safety.

Quality. The principal quality problem is not simply whether a study reports improvement, but whether the intervention is reproducible and the evidence is sufficiently robust for policy use. Frequent limitations include incomplete characterization of mineral/thermal resources, variable treatment temperature and dose, co-interventions, limited blinding, small samples, heterogeneous outcomes and inconsistent adverse-event reporting [2–6]. For health-system use, quality also requires appropriate patient selection, trained personnel, facility-level safety and documented clinical governance.

Cost-effectiveness. The recent economic literature is much less mature than the clinical literature. A 2026 systematic review with French health-insurance modelling estimated potentially meaningful savings from reduced analgesic and NSAID consumption after rheumatology-oriented spa treatment, while explicitly acknowledging heterogeneity and modelling limitations [13]. A 2022 regional analysis in Spain reported positive economic and social value, but it was not a clinical health-technology assessment [14]. Formal trial-based QALY evidence remains sparse in the recent five-year window; an important randomized economic evaluation in knee osteoarthritis predates the review period and is included only as contextual evidence [15].

1. Scope and review approach

1.1 Scope

The agreed deliverable is a scientific report critically reviewing recent data on quality, safety, efficacy and cost-effectiveness of Hydro/Balneotherapy. The present document therefore focuses primarily on evidence published from January 2021 through September 2026. Older studies are cited only when they provide important context that has not yet been replaced by recent evidence, particularly in health economics.

1.2 Review approach

This is a targeted critical review rather than a new systematic review or meta-analysis. Priority was given to systematic reviews, meta-analyses, Cochrane reviews, randomized controlled trials, recent economic evaluations and current WHO documents. Evidence was interpreted by intervention type, clinical indication, methodological quality, safety reporting and relevance to health-system decision-making. No new pooled effect estimates were calculated by FEMTEC.

- Primary evidence window: 2021–September 2026.
- Priority evidence: systematic reviews/meta-analyses, randomized trials and economic evaluations.
- WHO policy context: current strategy emphasizing evidence, quality, safety, regulation and appropriate integration of TCIM [1].
- Older economic studies: used only as contextual benchmarks where recent QALY-based analyses are sparse.

1.3 Terminology

Term	Use in this report
Hydrotherapy / aquatic therapy	Therapeutic use of water, including aquatic exercise or immersion; water is not necessarily natural mineral or thermal water.
Balneotherapy	Therapeutic use of natural mineral and/or thermal waters, generally in medically supervised treatment settings.
Spa therapy	Potentially multimodal programme that may combine balneotherapy with peloids, exercise, education, rehabilitation and other interventions.
Peloid / mud therapy	Therapeutic application of natural or processed semisolid materials, often used with thermal exposure; analysed separately when possible.

2. Quality of evidence and quality of delivery

2.1 Quality of the evidence base

A central finding of the recent literature is the discrepancy between frequently positive clinical signals and the certainty with which those signals can be translated into practice or policy. The 2021 umbrella review of medical hydrology identified potential benefit in several musculoskeletal conditions and chronic venous insufficiency, but concluded that the body of evidence still had important limitations [2]. This concern was reinforced by the 2025 BMJ Open review: across 42 randomized trials in rheumatology, the pooled estimates for pain and quality of life were favourable, yet both primary outcomes were graded as very low-certainty evidence [3].

- Risk of bias remains frequent, especially where blinding is difficult and outcomes are subjective.

- Interventions are heterogeneous: mineral composition, water temperature, exposure duration, treatment frequency and co-interventions differ substantially.
- Comparators range from usual care and waiting lists to tap-water or other placebo-like interventions.
- Outcome measures and follow-up intervals vary, limiting comparability and quantitative synthesis.
- Publication bias and selective or optimistic interpretation have been identified as concerns in recent evidence syntheses [3].
- Adverse events are often not defined or collected systematically.

2.2 Intervention characterization as a quality requirement

For hydrotherapy and especially balneotherapy, reproducibility requires more than naming the intervention. A technically adequate report should describe the therapeutic resource and the exposure sufficiently for another centre to reproduce it. Recent osteoarthritis and dermatology reviews repeatedly highlight heterogeneity and limitations in study quality [4,12].

- source and classification of the natural therapeutic resource;
- principal mineral/chemical characteristics when natural mineral water is used;
- temperature at source and/or application temperature;
- immersion depth or application modality;
- duration and frequency of each session and total number of sessions;
- concurrent exercise, medication, peloid therapy, education or rehabilitation components;
- patient selection, relevant contraindications and clinical supervision;
- predefined outcomes, follow-up intervals and adverse-event collection.

2.3 Quality of clinical delivery

For health-system use, quality also includes the conditions under which the intervention is delivered. Consistent with WHO's current TCIM strategy, evidence-informed integration should be accompanied by attention to safety, regulation, practitioner competence, quality assurance and appropriate service delivery [1]. For medically indicated hydro/balneotherapy, a practical quality framework should therefore include:

- medical indication and risk stratification;
- appropriately trained personnel and clear professional responsibilities;
- documented treatment parameters and individualized prescription where relevant;
- water/resource quality control and facility hygiene;
- accessibility, fall prevention and emergency preparedness;
- documentation of outcomes, withdrawals and adverse events;
- clear distinction between medically supervised treatment and unsupervised wellness use.

3. Efficacy

3.1 Overall evidence

The most comprehensive recent rheumatology synthesis included 42 randomized trials (29 mechanical disorders, 9 inflammatory diseases and 4 fibromyalgia trials). Balneotherapy was associated with lower pain (SMD −0.72; 95% CI −1.00 to −0.44) and higher quality of life (SMD 0.56; 95% CI 0.37 to 0.75) at approximately 3 months, but both outcomes were graded as very low certainty [3]. These estimates should therefore be read as a signal of possible benefit rather than definitive proof of a broadly applicable treatment effect.

3.2 Osteoarthritis

Osteoarthritis, particularly knee osteoarthritis, has one of the largest recent evidence bases. A 2023 systematic review of 17 studies of thermal mineral-water balneotherapy found improvement in commonly assessed outcomes such as pain and quality of life, while emphasizing that the quality of many included studies was not high [4]. A 2024 meta-analysis of six randomized hydrotherapy trials reported short-term reductions in pain and improvement in WOMAC scores at 1, 4 and 8 weeks; the authors judged the overall quality of evidence to be low and noted methodological weaknesses [5]. A 2025 review restricted to recent studies identified 13 randomized or quasi-randomized trials, with PEDro scores from fair to excellent, but substantial heterogeneity prevented meta-analysis [6].

Critical interpretation. The direction of effect is generally favourable for pain and physical function, but the evidence should not be summarized simply as 'proven efficacy'. The most defensible conclusion is that hydrotherapy/balneotherapy may be a useful adjunct within multimodal osteoarthritis care, with confidence limited by heterogeneity, risk of bias and short or inconsistent follow-up.

3.3 Chronic low back pain and back pain

A randomized clinical trial of 113 adults with chronic low back pain compared therapeutic aquatic exercise with physical therapy modalities and found greater improvement in disability, pain and several secondary outcomes after the 3-month intervention, with differences persisting through 12 months [7]. A 2025 systematic review of seven recent randomized or quasi-randomized balneotherapy studies reported that current data indicate potential improvement in pain and health-related quality of life, but treatment protocols and outcomes were too heterogeneous for meta-analysis; PEDro scores ranged from 3 to 9 [8].

Critical interpretation. The evidence is compatible with clinically relevant benefit, especially as part of active rehabilitation, but aquatic exercise and mineral-water balneotherapy should not be treated as identical interventions.

3.4 Fibromyalgia

A 2024 meta-analysis of 16 randomized trials of balneotherapy in fibromyalgia reported reductions in pain intensity and disability at the end of treatment, with effects on these outcomes persisting at 1, 3 and 6 months; effects on depression varied by time point [9]. A separate 2024 systematic review of four recent aquatic-exercise trials found positive results for pain and quality of life, while noting that benefits may be comparable to other exercise modalities and should be individualized [10].

Critical interpretation. Fibromyalgia is a reasonable target for further evidence-based use and study of both balneotherapy and aquatic exercise, but the mechanisms and components of benefit are likely multifactorial and not attributable solely to mineral content.

3.5 Chronic venous insufficiency

The 2023 Cochrane review included nine randomized trials with 1,126 participants. Compared with no treatment, balneotherapy probably slightly improved disease severity scores (moderate-certainty evidence) and may improve pain (low-certainty evidence). Effects on health-related quality of life were low to very low certainty, and comparisons with other active treatments were based on very limited evidence [11].

3.6 Dermatological indications

A 2024 systematic review of thermal mineral-water balneotherapy for dermatological diseases included eight studies, mainly in psoriasis, and reported improvement in signs and symptoms across included studies. However, the authors considered the evidence insufficiently robust because studies were limited in number and often of low quality [12].

3.7 Evidence summary

Area	Recent evidence	Main signal	Critical appraisal
Rheumatology overall	42 randomized trials; BMJ Open 2025 [3]	Pain and QoL estimates favoured balneotherapy	Very low certainty; high risk of bias, inconsistency and suspected publication bias.
Osteoarthritis	Systematic reviews 2023–2025; hydrotherapy meta-analysis 2024 [4–6]	Generally favourable pain/function outcomes	Heterogeneous interventions; overall certainty remains limited.
Back pain / CLBP	RCT 2022; recent systematic review 2025 [7,8]	Potential improvement in disability, pain and HRQoL	Aquatic exercise and balneotherapy are not interchangeable; study protocols vary.
Fibromyalgia	Meta-analysis and systematic review 2024 [9,10]	Pain, disability and QoL may improve	Positive signal, but intervention components and comparators vary.
Chronic venous insufficiency	Cochrane 2023 [11]	Small improvement in severity and pain	Certainty ranges from moderate to very low by outcome.
Dermatology	Systematic review 2024 [12]	Improvement reported mainly in psoriasis	Small evidence base; quality often low.

4. Safety

4.1 What the recent trials show

The best recent broad safety synthesis remains the 2025 review of randomized balneotherapy trials in rheumatology. Among 42 included trials, withdrawal was reported in 13 trials (2,062 participants), adverse events in only 5 trials (1,123 participants), and serious adverse events in only 2 trials (406 participants). The pooled relative risk was inconclusive for withdrawal (RR 0.75; 95% CI 0.46–1.20), adverse events (RR 0.80; 95% CI 0.43–1.50), and serious adverse events (RR 1.01; 95% CI 0.36–2.85) [3].

The 2024 knee-osteoarthritis hydrotherapy meta-analysis reported no serious adverse events attributable to hydrotherapy and no significant difference in adverse events between groups in the trials that reported them; adverse-event evidence was nevertheless graded low quality [5]. The Cochrane review in chronic venous insufficiency likewise found no clear difference in adverse effects, but certainty was low [11].

4.2 Sources of clinical risk

Safety should be considered across three interacting domains: patient-related risk, intervention-related risk and facility/environmental risk.

Domain	Examples	Implication
Patient	Cardiovascular/respiratory instability, impaired thermoregulation, severe mobility limitation, altered consciousness/seizure risk, active infection, compromised skin integrity.	Eligibility should depend on clinical stability, comorbidities, exposure parameters and supervision.

Domain	Examples	Implication
Intervention	Dizziness/hypotension, fatigue or thermal intolerance, transient symptom exacerbation, skin reactions, falls or transfer difficulties.	Treatment parameters and monitoring should be individualized; adverse events should be prospectively documented.
Facility / environment	Water microbiology, temperature control, hygiene, accessibility, fall prevention, equipment maintenance, staff competence, emergency preparedness.	Clinical safety cannot be separated from facility-level quality assurance.

4.3 Safety reporting as an evidence gap

The small proportion of trials contributing adverse-event data is itself an important finding. Future trials and service evaluations should define adverse events and serious adverse events in advance, specify whether surveillance is active or passive, report timing and severity, distinguish treatment-related events from underlying disease, and report withdrawals due to harms. This is essential if the evidence is intended to inform health policy.

5. Cost-effectiveness and economic evidence

5.1 Recent evidence

Economic evidence is substantially less developed than evidence on clinical outcomes. The most recent study identified for this report was published in 2026. Montastruc and Bouvier performed a systematic review and a French health-insurance economic evaluation focused on reduced drug consumption after balneotherapy. Of 48 randomized trials identified, eight rheumatology trials were used for the economic modelling. Applying 2024 French reimbursement data to 441,776 patients who underwent rheumatology-oriented spa treatment, estimated six-month savings associated with reduced NSAID consumption ranged from €0.05 million to €1.03 million (mean approximately €0.505 million), while estimated analgesic savings ranged from €0.73 million to €2.31 million (mean approximately €1.547 million) [13].

Critical interpretation. This analysis is relevant because it translates medication reduction into health-system costs, but it is not a randomized trial-based cost-utility analysis. The estimates depend on French utilization and reimbursement assumptions, the selected RCTs were heterogeneous, and the results should not be extrapolated directly to other health systems.

A 2022 study in the Maresme region of Spain examined the economic and social value of balneotherapy/spa tourism using an input-output model and cost-benefit analysis. It reported an economic multiplier of 1.529 for direct and indirect effects (1.712 including induced effects) and a social cost-benefit ratio of 1.858 [14]. This is useful for regional policy and social-value discussions, but it is conceptually different from clinical cost-effectiveness or cost-utility analysis.

5.2 Older trial-based evidence as context

Because formal recent QALY-based evaluations are sparse, one older randomized economic evaluation remains informative as background. In a 2017 knee-osteoarthritis trial, mud-bath therapy plus usual care generated more QALYs over 12 months than usual care alone (0.835 vs 0.753) and lower average direct health-care costs (€303 vs €975); the authors classified the intervention as economically dominant in their trial setting [15]. This study predates the five-year review window and should not be treated as current proof of cost-effectiveness across systems.

5.3 What is still needed

- prospective health-economic analyses embedded in contemporary randomized or pragmatic trials;
- predefined health-system and societal perspectives;

- QALYs and validated utility instruments;
- direct medical costs, patient out-of-pocket costs and indirect costs;
- medication use, hospital/ambulatory utilization and rehabilitation utilization;
- return-to-work, absenteeism, caregiver burden and productivity where relevant;
- longer follow-up and sensitivity analyses;
- country-specific analyses rather than unqualified international extrapolation.

6. Results and discussions/ interpretation

Across the four domains, the evidence presents a coherent but nuanced picture. Hydrotherapy and balneotherapy are not unsupported interventions; there is a recurring signal of symptomatic and functional benefit in selected populations. At the same time, the confidence placed in these effects is constrained by methodological weaknesses and by the fact that the labels 'hydrotherapy', 'balneotherapy' and 'spa therapy' often represent clinically different interventions.

Domain	Current assessment	Implication
Quality	Major limitation. Evidence quality and intervention reporting are inconsistent.	Standardization and transparent reporting are prerequisites for stronger policy conclusions.
Efficacy	Favourable signal in selected conditions, strongest evidence base in musculoskeletal care.	Use as an adjunct within evidence-based care is more defensible than broad disease-independent claims.
Safety	Short-term tolerability appears acceptable in selected supervised populations; rare harms are poorly estimated.	Prospective safety surveillance and facility-level quality control are required.
Cost-effectiveness	Promising but sparse and system-specific recent evidence.	New prospective health-economic studies are needed before general reimbursement conclusions.

7. Database Research and priorities

1. Use precise intervention terminology and avoid pooling fundamentally different water-based interventions without justification.
2. Register protocols and statistical analysis plans prospectively.
3. Use adequate randomization, allocation concealment and blinded outcome assessment where participant blinding is not feasible.
4. Use placebo-like or attention-matched comparators when scientifically and ethically feasible.
5. Characterize natural mineral/thermal resources and treatment dose in sufficient detail for reproducibility.
6. Define core clinical outcomes and standardized follow-up time points by condition.
7. Collect adverse events prospectively using predefined definitions and report withdrawals due to harms.
8. Include multicentre and pragmatic trials that reflect routine clinical practice.
9. Build contemporary health-economic evaluation into clinical trials, including QALYs and resource utilization.
10. Separate clinical effectiveness from broader tourism or regional economic impact when making health-system decisions.

8. Conclusion

Recent evidence supports the clinical relevance of hydrotherapy and balneotherapy for selected indications, particularly musculoskeletal disorders, while also showing that the certainty of evidence remains variable and often low. The most important next step is not simply to accumulate more positive studies, but to improve methodological

quality, intervention standardization, safety surveillance and health-economic evaluation. Within those conditions, hydrotherapy and balneotherapy can be evaluated as components of evidence-informed, person-centred rehabilitation and integrative care.

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