

CONSTRUCTION OF A VALUE ASSESSMENT FRAMEWORK FOR NEW ANTIDIABETIC DRUGS TO SUPPORT EVIDENCE-INFORMED DECISION-MAKING

ACCEPTANCE CODE

HTA 16

Integrating effectiveness, patient-reported outcomes, safety and affordability for evidence-informed decisions

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Background & objective

- New antidiabetic drugs deliver benefits beyond glycaemic control, but their value spans clinical outcomes, patient experience, safety and affordability.
- Existing value frameworks are often generic, insufficiently patient-centred and difficult to use when evidence is heterogeneous.
- Objective: develop and pilot-apply a transparent MACBETH-based multi-criteria value assessment framework for new antidiabetic drugs.

Decision need

Make multidimensional trade-offs explicit so clinicians, payers and policymakers can compare value with a shared, auditable structure.

Study design

- Evidence synthesis**
Systematic review, clinical trials, real-world evidence and China price data
- Criterion development**
Literature review + focus group with 10 stakeholders, including 4 people with diabetes
- MACBETH elicitation**
15 stakeholders compared qualitative differences in attractiveness; value functions and weights derived
- Drug assessment**
Six drugs scored on nine criteria using an additive value model
- Uncertainty checks**
One-way sensitivity analysis and robustness analysis within ±5% input perturbations

Model logic

Overall value = sum of criterion-specific value scores × criterion weights.
Piecewise linear value functions put outcomes on a common preference scale.

Value framework

Four domains and nine quantitative criteria

Comparative effectiveness

- HbA1c change
- Weight loss
- MACE risk
- Heart failure hospitalization
- Diabetic kidney disease

Patient-reported outcomes

- HRQoL improvement

Comparative safety

- Mild/moderate AEs
- Serious AEs

Affordability

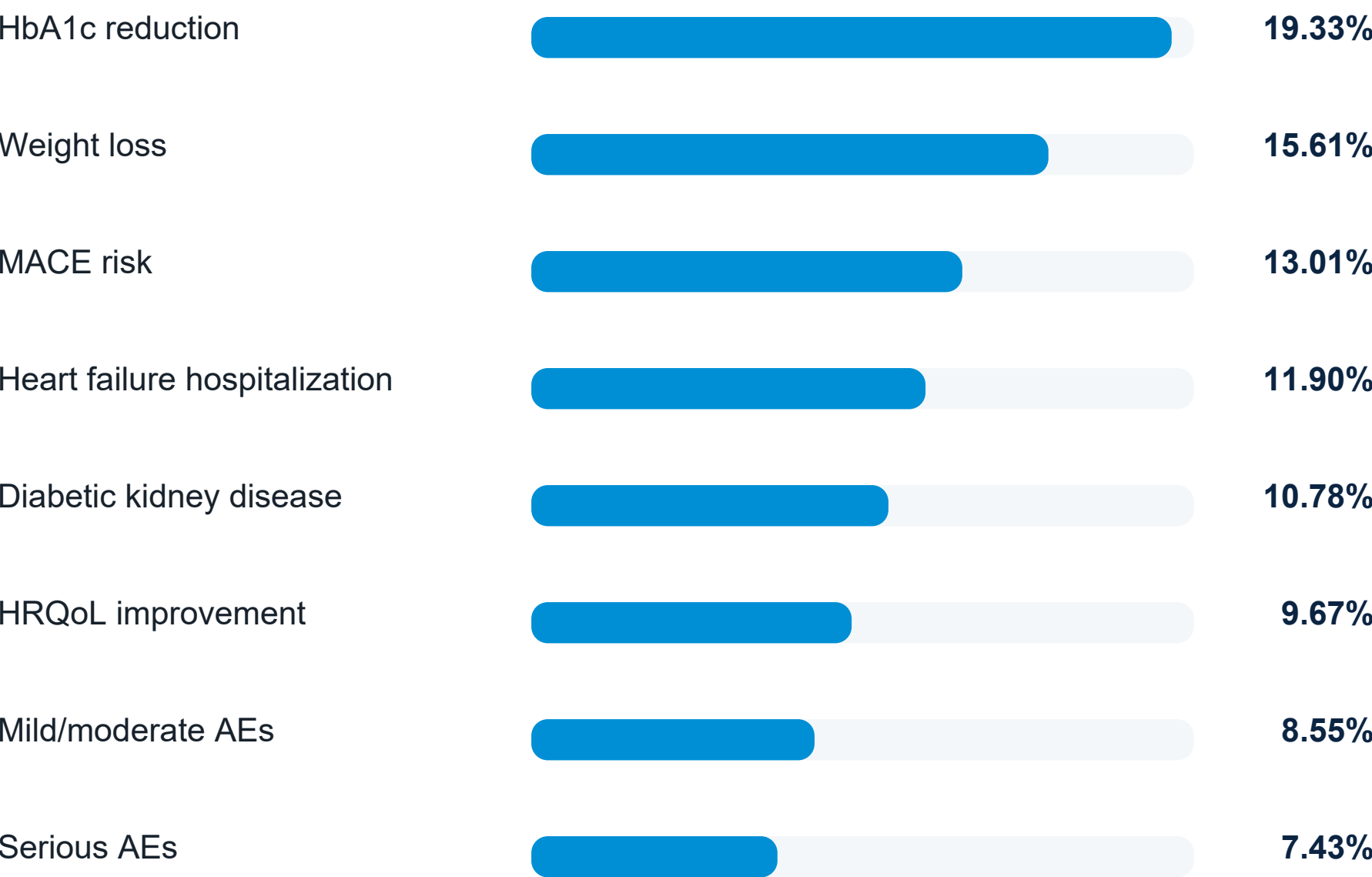
- Annual out-of-pocket cost

Why MACBETH?

Experts express qualitative judgments (no difference to extreme difference). The software converts consistent judgments into cardinal value scales and weights, reducing arbitrary direct scoring.

Criterion weights

Effectiveness dominated the value model

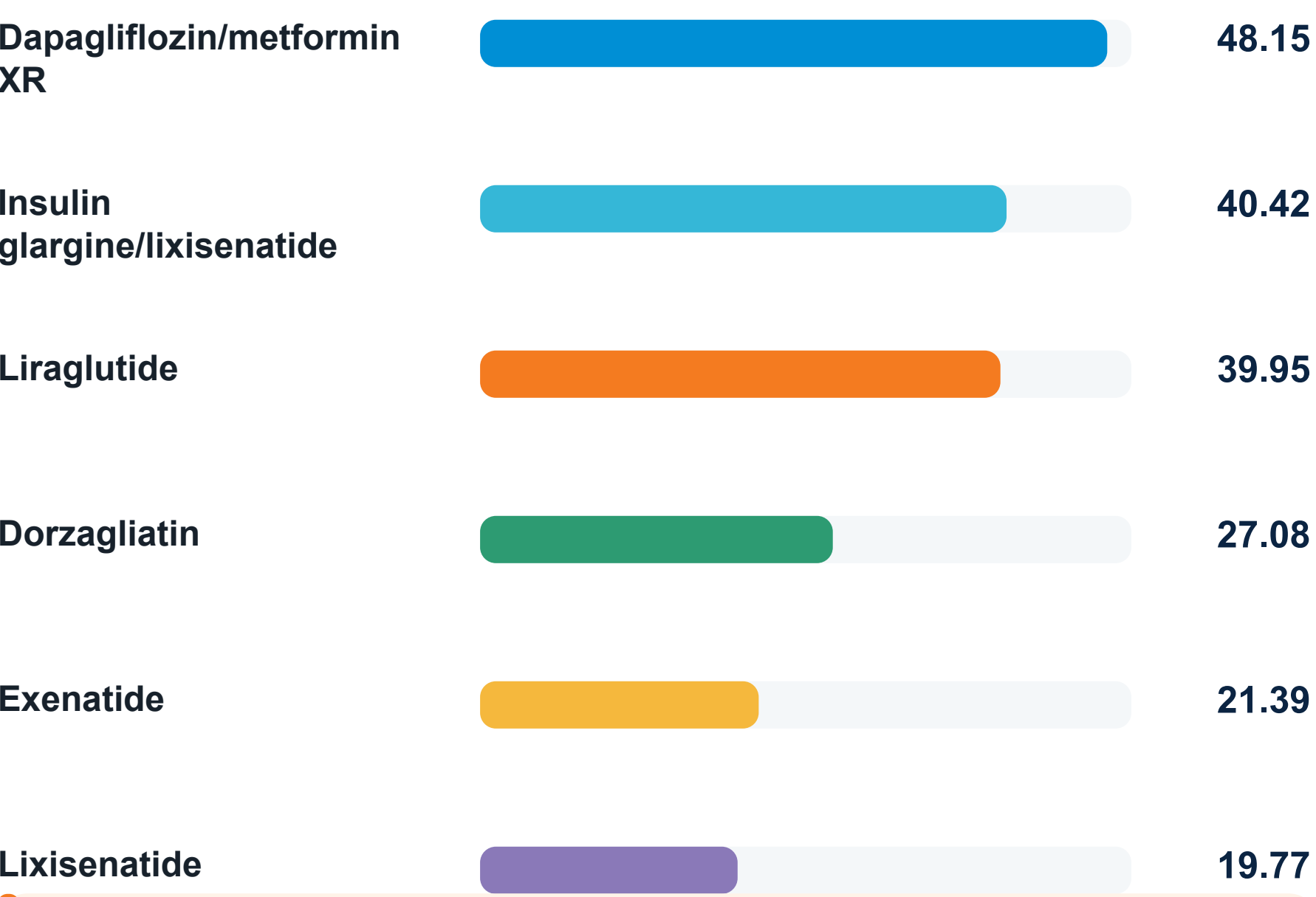


Top three weights

HbA1c reduction (19.33%), weight loss (15.61%) and MACE risk reduction (13.01%) together account for 47.95% of total weight.

Overall value scores

Six new antidiabetic drugs; score range 0-100



Leading profile

Dapagliflozin/metformin XR ranked first (48.15), driven by strong HRQoL improvement and annual out-of-pocket cost performance.

How to interpret the ranking

- The ranking is a structured value comparison, not a clinical treatment recommendation. It combines evidence across outcomes that use different units.
- Dapagliflozin/metformin XR scored 100.00 on HRQoL improvement and 96.59 on annual out-of-pocket cost savings.
- Insulin glargine/lixisenatide showed a notable advantage in MACE risk reduction (58.18).
- Lixisenatide ranked lowest (19.77), with limited contributions from glycaemic, weight, cardiovascular and renal criteria.

Decision use

The framework can support reimbursement review, rational drug selection and value-based diabetes care by showing both the overall score and the dimensions that create it.

Robustness of findings

- Sensitivity analysis: dapagliflozin/metformin XR remained the highest-ranked drug across the nine criteria.
- Robustness analysis: all rankings remained unchanged when attribute weights and performance scores were adjusted within ±5%.
- Large, implausible changes in key weights would be required to alter the ranking.

Stability signal

The model conclusion is stable within the tested uncertainty range, supporting use as a transparent decision-support tool.

Implications

- For payers: compare benefit, safety and affordability on a single auditable scale.
- For clinicians: complement guideline evidence with patient-reported outcomes and economic burden.
- For patients: make lived experience and affordability visible in value construction.
- For living HTA: update value functions when new cardiovascular, renal, long-term or real-world evidence becomes available.

Key message

Value assessment is strongest when evidence, preferences and uncertainty are shown together - not when the decision is reduced to a single endpoint.

Strengths & limitations

Strengths

- Evidence-driven criteria and stakeholder-informed weights
- Standardized piecewise linear value functions
- Explicit sensitivity and robustness testing

Limitations

- Budget impact and incremental cost-effectiveness ratios were not included because comparable data and thresholds were limited.
- Expert judgments retain some subjectivity and may differ across stakeholder groups.
- No sex- or gender-stratified analyses were conducted.

Conclusion

A transparent MACBETH-based framework can help translate multidimensional antidiabetic drug evidence into evidence-informed reimbursement and care decisions.