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A FRAMEWORK FOR LIFECYCLE ASSESSMENT AND REPOSITIONING OF BIOLOGIC THERAPIES INFORMED BY CROSS-COUNTRY EVIDENCE AND STAKEHOLDER RECOMMENDATIONS

Biosimilar-Enabled Access and Repositioning (BEAR)

Background

- Biologic medicines represent >40% of global pharmaceutical spend. When originator patents expire, biosimilar competition is expected to lower prices, broaden access and improve outcomes; yet that promise remains largely unrealized.
- Biologic adoption decisions at launch are rarely revisited. Biosimilars' value is seen narrowly — cost savings from price competition in the originally reimbursed indications — and is seldom reassessed even when a redefined value proposition is possible.
- Yet biosimilar price competition can unlock more than savings: where it lowers therapy cost, a product can be reassessed for expanded populations, indications and treatment lines — benefiting patients, payers, health systems and industry.
- Value is dynamic, interdependent and global — but assessment remains static and country-level, leaving value on the table. No shared framework guides when, how or by whom reassessment should be triggered.

Objectives

- Develop a structured Biosimilar-Enabled Access and Repositioning (BEAR) framework — how biosimilar entry triggers reimbursement, guideline and formulary changes that broaden value-based eligibility beyond affordability gains.
- Examine the global evidence base, model case studies to quantify value, and derive implementation recommendations through expert elicitation.

Methods

- **Scoping** — structured review of the global evidence base; development of the analytical BEAR framework (Figure 1), structured around what triggers reassessment, how the process unfolds, and what impact it has.
- **Evidencing** — 25 documented cases screened; an illustrative subset selected to span geographies, system types and all five channels (Table 1); two cases modelled in depth (denosumab, US; bevacizumab, England).
- **Translating** — Findings validated and implementation recommendations developed through expert elicitation and a steering-committee workshop.

The BEAR framework

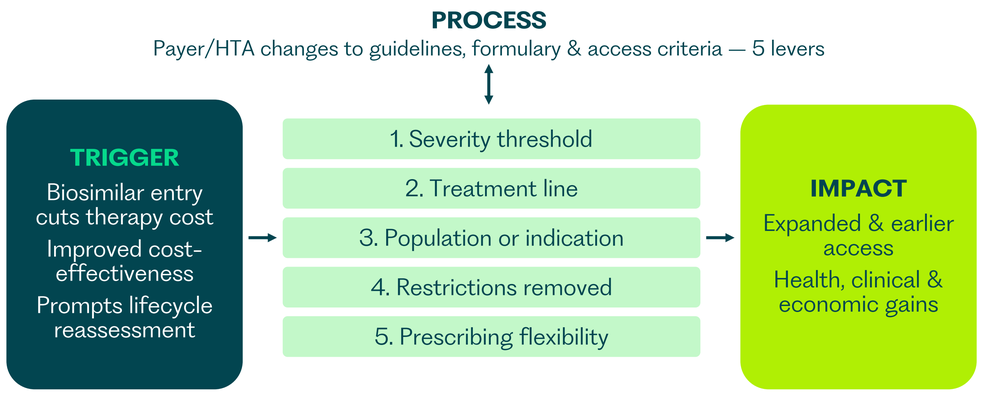

Figure 1. The BEAR framework

Global evidence for BEAR — illustrative cases across systems & channels

Biologic (country)	System	Channel	Illustrative access impact
Natalizumab (England)	NICE	Severity threshold broadened	Expanded eligibility to highly active RRMS (~43,000 patients).
Bevacizumab (England) ▲	NICE	Treatment-line advancement	Enabled access for 7,000+ additional patients with metastatic colorectal cancer (mCRC).
Adalimumab (New Zealand)	PHARMAC	Population / indication expansion	700+ additional patients in the first year (base ~6,400).
Tocilizumab (United States)	CMS	Line advancement + population expansion	Earlier access after first TNFi failure (~1.3M US adults with RA).
Rituximab (Australia)	PBAC	Removal of restrictions	From authority-required to unrestricted use; funded access across five autoimmune conditions.
Denosumab (United States) ▲	CMS	Removal of restriction (modelled, theoretical)	Could expand eligibility to ~3.18M osteoporosis patients at high risk of fracture; downstream fracture-cost savings.
Filgrastim (Sweden)	TLV	Liberalised prescribing	~5× regional G-CSF use; savings ≈ 4—5% of the regional medicine budget / year.
Infliximab (Canada)	Provincial plans	Non-medical switching (substitution)	Modelled CAD 46,194 lower total cost per patient over 5 years (Crohn's disease).

Table 1. ▲ modelled in depth to quantify value (below). Seven BEAR cases map to the five channels across five health systems; infliximab (Canada) is shown as a biosimilar-switching / substitution comparator.

Denosumab case study (United States) - osteoporosis (OP)

+2.7M patients **492,366** fractures **214,033** QALYs **$10.5B** NMB

- **Substitution alone** — $12.02B: holding uptake constant, biosimilar entry cuts cumulative spend from $21.75B to $9.73B, with no change to coverage, guidelines or patients treated.
- **With reassessment (BEAR)** — $22.9B in fracture cost-offsets, almost doubling the $12.02B price-competition savings, plus $10.5B net monetary benefit.
- For chronic progressive conditions, lower biosimilar prices make earlier intervention cost-saving by slowing progression and reducing downstream expenditure.

Table 2. Denosumab base-case outcomes by population (US payer; lifetime; 3% discount)

Population	Add'l patients	Fractures prevented	Cost-offsets ($B)	QALYs	NMB ($B)
Women with OP	1,700,000	324,843	$15.1	141,749	$7.1
Men with OP	680,000	86,889	$4.1	38,587	$1.5
Glucocorticoid Induced OP	318,750	80,634	$3.7	33,697	$1.9
Combined	**2,698,750**	**492,366**	**$22.9**	**214,033**	**$10.5**

NMB at $150,000/QALY WTP; combined ICER $100,921/QALY (within the $100k—$150k range). WOP is the largest group and greatest opportunity.

Bevacizumab (England) - metastatic colorectal cancer

7,000+ newly eligible **2,170** QALYs **£20.8M** NMB

- **Substitution alone** — £132M saved by switching to a lower-cost biosimilar across bevacizumab's four already-recommended indications.
- **With reassessment** — price competition brought the mCRC ICER to £20,378/QALY, within NICE's threshold, generating £20.8M NMB over three years.

NMB at £30,000/QALY, the upper bound of NICE's cost-effectiveness threshold range (£20,000-£30,000 per QALY) at the time of the research. The range is now £25,000-£35,000/QALY.

Workshop recommendations

- **Alignment** — formal policies for routine reassessment after loss of exclusivity; joint working across HTA bodies, guideline developers and payers; bottom-up routes in decentralised systems.
- **Evidence** — invest in real-world evidence and novel methods (e.g. modelling, Bayesian); public-sector incentives to counter free-riding on evidence.
- **Education** — raise awareness of BEAR's value, tailored to system type (e.g. payer education via AMCP in the US); upskill patient and clinical groups to engage with HTA.
- **Dialogue** — structured early dialogue among manufacturers, regulators, HTA bodies and payers; horizon scanning ~18—24 months pre-loss-of-exclusivity.

Conclusion

- **Overlooked value:** BEAR can unlock substantial value for patients, health systems and industry, yet is overlooked.
- **Already applied:** health systems worldwide use BEAR, but in isolation and in divergent ways.
- **System-specific routes:** case studies show the same gains via HTA reassessment (England), reinvested savings (New Zealand) or relaxed prescribing (Australia, Sweden). Without a standard route, as in the US, value remains largely unrealised; the denosumab model shows what is forgone.
- **Barriers:** misaligned incentives, free-riding and limited HTA capacity, offset by tailored stakeholder engagement and robust evidence, including RWE.
- **Standard practice** needs alignment, education, early dialogue and robust evidence.

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