Professional Certificate in Health Economics and Market Access

Pricing and Reimbursement Policies

Absorption Rate (related terms: Market uptake, diffusion) – the speed at which a new therapy is adopted by prescribers after launch. Example: A drug with a high absorption rate may reach 50% market share within six months, influencing pricing negotiations. Challenge: Predicting absorption accurately requires robust real-world data, and overestimation can lead to unsustainable price expectations.

Access Scheme (related terms: Risk-sharing, managed entry) – a policy tool that allows patients early or continued access to a medicine under specific conditions, often tied to evidence collection. Example: The UK's Cancer Drugs Fund provides temporary access while additional data are gathered. Challenge: Balancing rapid patient access with the need for cost-effectiveness evidence can strain budgets.

Affordability Index (related terms: Budget impact, willingness-to-pay) – a metric that compares the cost of a therapy to a population's ability to pay, often expressed as a percentage of GDP per capita. Example: A drug costing 0.8 % Of GDP per capita may be deemed unaffordable in low-income settings. Challenge: Variability in health-care financing structures makes cross-country comparisons difficult.

Agreement on Price (related terms: Price negotiation, confidential discount) – the final settlement between a manufacturer and a payer that sets the reimbursable price, which may include rebates or volume-based discounts. Example: A 15 % confidential discount may be granted in exchange for a formulary placement. Challenge: Lack of transparency can impede external reference pricing and market competition.

Anchor Price (related terms: Reference price, price ceiling) – a benchmark price used by payers to set the maximum reimbursable amount for therapeutic class drugs. Example: In some EU countries, the anchor price is derived from the lowest priced product in the class. Challenge: Manufacturers may strategically price one product low to shift the anchor for competitors.

Annualized Cost (related terms: Total cost of ownership, cost per patient-year) – the average cost incurred each year over the expected duration of therapy, facilitating comparison across treatments with different dosing schedules. Example: A drug administered every six months may have a lower annualized cost than a daily oral therapy despite higher unit price. Challenge: Requires assumptions about adherence and discontinuation rates.

Application Dossier (related terms: Submission package, regulatory filing) – the collection of clinical, economic, and pricing information submitted to health authorities for market authorization and reimbursement consideration. Example: A dossier may include a health-technology assessment (HTA) report, budget impact analysis, and pricing justification. Challenge: Aligning regulatory and HTA evidence requirements can increase preparation time and cost.

Assessment Framework (related terms: HTA methodology, decision-analytic model) – the structured approach used by HTA bodies to evaluate clinical benefit, cost-effectiveness, and broader societal impact. Example: NICE's "Technology Appraisal Guidance" follows a defined framework that incorporates QALYs and

ICER thresholds. Challenge: Divergent frameworks across jurisdictions hinder multinational pricing strategies.

Benefit-Risk Ratio (related terms: Therapeutic value, safety profile) – a comparative measure that weighs the clinical benefits of a therapy against its associated risks, informing reimbursement decisions. Example: A high benefit-risk ratio may justify premium pricing for a breakthrough oncology drug. Challenge: Quantifying risk in monetary terms is often subjective and varies among stakeholders.

Bundled Payment (related terms: Episode-based payment, capitation) – a reimbursement model where a single payment covers all services related to a defined episode of care, encouraging cost-containment. Example: A bundled payment for joint replacement may include the implant, surgery, and post-acute rehabilitation. Challenge: Determining the appropriate bundle size and ensuring quality outcomes require robust data collection.

Budget Impact Analysis (BIA) (related terms: Cost-impact model, fiscal projection) – an economic evaluation that estimates the financial consequences of adopting a new therapy within a specific budget horizon. Example: A BIA may project a 2 % increase in oncology spend over five years after introducing a novel immunotherapy. Challenge: Accurate forecasts depend on assumptions about market share, price, and patient eligibility.

Capitation Rate (related terms: Per-member-per-month, fixed fee) – a predetermined amount paid per enrollee to cover a defined set of services, shifting financial risk to providers. Example: Primary care physicians may receive a monthly capitation fee to manage chronic disease patients. Challenge: Setting rates that reflect true service costs while avoiding under-utilization is complex.

Cost-Effectiveness Threshold (related terms: Willingness-to-pay, ICER ceiling) – the maximum incremental cost per quality-adjusted life-year (QALY) that a payer is prepared to accept for a health-care intervention. Example: The UK commonly uses £20,000–£30,000 per QALY as its threshold. Challenge: Thresholds may not reflect societal preferences or budget constraints, leading to inconsistent decisions.

Cost-Utility Analysis (CUA) (related terms: QALY, health state valuation) – a form of economic evaluation that compares costs with outcomes measured in utility-adjusted units, such as QALYs. Example: A CUA may demonstrate that a new anticoagulant yields 0.05 Additional QALYs at an incremental cost of $2,500, resulting in an ICER of $50,000/QALY. Challenge: Utility measurement can vary by instrument and cultural context.

Coverage Determination (related terms: Formulary inclusion, reimbursement decision) – the official decision by a payer regarding whether a product will be reimbursed, and under what conditions. Example: A coverage determination may restrict a drug to third-line use only. Challenge: Frequent revisions to coverage criteria can create uncertainty for manufacturers and clinicians.

Confidential Discount (related terms: Price rebate, net price) – a reduction in the list price that is not disclosed publicly, often negotiated in confidential agreements. Example: A manufacturer may provide a 20 % confidential discount to a national health service in exchange for market exclusivity. Challenge: Confidentiality hampers price transparency and can distort external reference pricing.

Conditional Approval (related terms: Accelerated pathway, post-marketing requirement) – regulatory authorization granted on the basis of preliminary evidence, contingent upon further data collection. Example: The FDA's "Accelerated Approval" program allows early market entry for oncology drugs while requiring confirmatory trials. Challenge: Payers must decide whether to reimburse before full efficacy data are available.

Cost-Minimisation Analysis (CMA) (related terms: Equivalence study, price comparison) – an economic evaluation used when clinical outcomes of interventions are proven equivalent, focusing solely on cost differences. Example: A CMA may compare two generic antibiotics with identical efficacy, selecting the lower-cost option. Challenge: Demonstrating true equivalence can be difficult, limiting the applicability of CMA.

Cost-Sharing (related terms: Co-pay, deductible) – a financial contribution required from patients at the point of service, intended to moderate utilization and share expenditure. Example: A $20 co-pay for each prescription may be applied to specialty drugs. Challenge: High cost-sharing can deter adherence, especially for chronic therapies.

Cross-Price Elasticity (related terms: Substitution effect, market competition) – the responsiveness of demand for a product to changes in the price of a competing product. Example: A 10 % price increase in Drug A may lead to a 5 % increase in demand for Drug B if they are close substitutes. Challenge: Accurate elasticity estimates require detailed market data and may vary across patient sub-populations.

Decision-Analytic Model (related terms: Markov model, simulation) – a structured quantitative framework that projects costs and health outcomes over time, supporting HTA and pricing decisions. Example: A Markov model may simulate disease progression for a chronic condition to estimate long-term cost-effectiveness. Challenge: Model validity depends on the quality of input data and assumptions about transition probabilities.

Discount Rate (related terms: Time preference, present value) – the factor used to convert future costs and benefits into present values, reflecting the preference for immediate outcomes. Example: A 3 % annual discount rate is commonly applied in health-economic evaluations. Challenge: Selecting an appropriate rate influences ICERs, and different jurisdictions may prescribe varying rates.

Discounted Cash Flow (DCF) (related terms: Net present value, investment appraisal) – a financial analysis technique that evaluates the present value of expected cash inflows and outflows, often used for pricing high-cost therapies. Example: A DCF model may assess the return on investment for a gene-therapy manufacturer over a 10-year horizon. Challenge: Uncertainty in long-term uptake and discount rates can affect valuation accuracy.

Drug Utilisation Review (DUR) (related terms: Prescribing audit, medication safety) – a systematic evaluation of prescribing patterns to ensure appropriate, safe, and cost-effective medication use. Example: DUR may identify over-prescription of high-cost antibiotics and recommend formulary changes. Challenge: Implementing DUR requires robust data infrastructure and clinician engagement.

Economic Evaluation (related terms: Cost-effectiveness analysis, budget impact) – the comparative analysis

of alternative interventions in terms of both costs and outcomes, forming the basis for reimbursement decisions. Example: An economic evaluation may combine a CUA with a BIA to inform a payer's pricing negotiation. Challenge: Integrating multiple evaluation types while maintaining methodological rigor can be resource-intensive.

External Reference Pricing (ERP) (related terms: Price benchmarking, cross-border comparison) – a pricing strategy where a jurisdiction sets a drug's price based on the price in other reference countries. Example: Germany may reference the lowest price among France, Italy, and Spain when negotiating a new oncology drug. Challenge: Confidential discounts and varying currencies complicate direct price comparison.

Fee-for-Service (FFS) (related terms: Activity-based payment, volume-driven reimbursement) – a payment model where providers are reimbursed for each individual service rendered, encouraging higher service volume. Example: Physicians may bill separately for consultation, lab tests, and procedures under FFS. Challenge: FFS can incentivize over-utilization and increase overall health-care costs.

Formulary Management (related terms: Therapeutic class, tiered access) – the process of selecting, organizing, and maintaining a list of approved medicines to guide prescribing and reimbursement. Example: A tier-1 formulary may include generic drugs with no prior authorization, while specialty drugs occupy tier-3. Challenge: Balancing clinical autonomy with cost containment requires stakeholder alignment.

Health Technology Assessment (HTA) (related terms: Cost-effectiveness, evidence synthesis) – a multidisciplinary evaluation of medical technologies that examines clinical effectiveness, safety, economic impact, and ethical considerations. Example: HTA agencies such as CADTH or NICE produce reports that directly influence reimbursement. Challenge: Harmonizing HTA standards across regions remains a global priority.

Incremental Cost-Effectiveness Ratio (ICER) (related terms: Incremental analysis, cost-utility) – the ratio of the difference in costs to the difference in health outcomes between two interventions, expressed as cost per QALY or life-year gained. Example: An ICER of $45,000/QALY may be deemed acceptable in the United States but above the threshold in Canada. Challenge: Interpretation of ICERs can be ambiguous when confidence intervals cross decision thresholds.

Indication-Specific Pricing (ISP) (related terms: Value-based pricing, multi-indication product) – a pricing approach that sets different prices for each therapeutic indication of a single product, reflecting its relative value. Example: A biologic may be priced higher for oncology than for rheumatology due to differing clinical benefits. Challenge: Implementing ISP requires robust tracking of indication-specific utilization and may increase administrative burden.

Individual Patient Funding Request (IPFR) (related terms: Compassionate use, exception request) – a formal application submitted by a clinician to obtain reimbursement for a patient who does not meet standard coverage criteria. Example: An IPFR may be filed for a rare disease patient requiring an off-label therapy. Challenge: Processing times can be lengthy, and outcomes are often unpredictable.

International Price Comparison (IPC) (related terms: ERP, price transparency) – the systematic analysis of drug prices across multiple countries to inform domestic pricing negotiations. Example: Manufacturers may

use IPC data to justify premium pricing in high-income markets. Challenge: Differences in health-system structures and discount confidentiality limit the comparability of IPC data.

Joint Powers Agreement (JPA) (related terms: Collaborative procurement, pooled purchasing) – an arrangement where multiple payers combine resources to negotiate a single price for a high-cost therapy. Example: Several regional health authorities may form a JPA to secure a volume discount on a hepatitis C cure. Challenge: Aligning governance and decision-making across independent entities can be complex.

Key Performance Indicator (KPI) (related terms: Outcome metric, quality measure) – a quantifiable metric used to assess the success of a pricing or reimbursement policy. Example: A KPI could be the reduction in average drug spend per patient after implementing a risk-sharing agreement. Challenge: Selecting KPIs that capture both financial and clinical outcomes requires careful planning.

Life-Cycle Management (LCM) (related terms: Product extension, portfolio strategy) – the strategic planning of a product's market presence from launch through patent expiry, including pricing adjustments and new indications. Example: LCM may involve introducing a fixed-dose combination to extend market exclusivity. Challenge: Anticipating competitor entry and regulatory changes is essential to maintain profitability.

Managed Entry Agreement (MEA) (related terms: Risk-sharing, conditional reimbursement) – a contractual arrangement that allows a new therapy to enter the market under specific performance-based conditions. Example: An outcome-based MEA may tie reimbursement to real-world survival rates. Challenge: Data collection and verification mechanisms must be robust to avoid disputes.

Markov Model (related terms: State transition, decision-analytic model) – a type of decision-analytic model that simulates patient movement among health states over discrete time cycles, commonly used in chronic disease CEAs. Example: A Markov model for heart failure may include states such as "stable," "hospitalized," and "death." Challenge: Defining appropriate cycle length and transition probabilities is critical for model credibility.

Maximum Reimbursable Price (MRP) (related terms: Price ceiling, tariff) – the highest price that a payer will agree to reimburse for a product, often set through negotiation or regulation. Example: In some jurisdictions, the MRP is linked to a percentage of the reference price. Challenge: Manufacturers may need to offer discounts or patient-access schemes to meet the MRP.

Market Access Strategy (related terms: Launch plan, stakeholder engagement) – a comprehensive plan that outlines how a product will achieve reimbursement, pricing, and uptake in target markets. Example: The strategy may include health-economic modeling, payer outreach, and real-world evidence generation. Challenge: Coordinating multiple activities across regions while respecting local regulations demands cross-functional expertise.

National Reimbursement List (NRL) (related terms: Formulary, covered drugs) – an official list of medicines that are approved for reimbursement within a country's public health system. Example: The NRL in Brazil includes all drugs that the Unified Health System (SUS) will pay for. Challenge: Updating the NRL to reflect new evidence can be administratively burdensome.

Net Price (related terms: List price, discount) – the actual price paid by a payer after accounting for all rebates, discounts, and other price concessions. Example: A drug with a list price of $10,000 and a 30 % confidential discount has a net price of $7,000. Challenge: Lack of transparency around net prices hampers comparative effectiveness assessments.

Outcome-Based Agreement (OBA) (related terms: Performance-linked payment, risk-sharing) – a type of MEA where reimbursement is contingent on achieving predefined clinical outcomes in real-world settings. Example: Payment may be reduced if the observed progression-free survival falls below a threshold. Challenge: Collecting reliable outcome data and attributing results to the therapy can be technically demanding.

Patient-Reported Outcome (PRO) (related terms: Health-related quality of life, questionnaire) – information directly reported by the patient about health status, symptoms, or treatment satisfaction, often used in economic evaluations. Example: PRO data from the EQ-5D instrument feed into QALY calculations. Challenge: Ensuring cultural validity and minimizing missing data are essential for robust analyses.

Pharmacoeconomic Evaluation (related terms: Cost-effectiveness, budget impact) – the systematic assessment of the value of a pharmaceutical product, integrating both economic and clinical dimensions. Example: A pharmacoeconomic study may compare a novel biologic with an existing standard of care in terms of cost per QALY. Challenge: Data gaps and methodological heterogeneity can limit the applicability of findings.

Pharmacovigilance (related terms: Safety monitoring, post-marketing surveillance) – the process of detecting, assessing, and preventing adverse effects of medicines after they have entered the market. Example: Pharmacovigilance data may trigger a price renegotiation if safety concerns emerge. Challenge: Timely reporting and analysis of safety signals are crucial but resource-intensive.

Price Cap (related terms: Maximum price, regulatory ceiling) – a statutory limit on the price that can be charged for a particular drug or therapeutic class. Example: Some countries impose a price cap on insulin to protect patients from unaffordable costs. Challenge: Caps may discourage innovation if they reduce expected returns on investment.

Price Discrimination (related terms: Tiered pricing, market segmentation) – the practice of charging different prices for the same product in different markets or to different payer groups, often based on ability to pay. Example: A manufacturer may offer lower prices to low-income countries while maintaining higher prices in high-income markets. Challenge: Managing parallel trade and maintaining price integrity across regions can be difficult.

Price Elasticity of Demand (PED) (related terms: Sensitivity, demand response) – a measure of how quantity demanded changes in response to a price change. Example: A PED of –0.8 Indicates that a 10 % price increase leads to an 8 % reduction in demand. Challenge: Estimating PED for specialty drugs is complicated by limited substitutes and payer controls.

Price Transparency Initiative (related terms: Open pricing, data disclosure) – policies or programs aimed at making drug price information publicly available to improve market efficiency. Example: The US

"Transparency in Coverage" rule requires insurers to publish negotiated rates. Challenge: Confidential discounts may still be hidden, limiting the impact of transparency measures.

Pricing Benchmark (related terms: Reference price, comparator) – a standard price used as a point of comparison during price negotiations or regulatory assessments. Example: A benchmark may be the price of the closest therapeutic alternative in the same class. Challenge: Selecting an inappropriate benchmark can lead to suboptimal pricing outcomes.

Pricing Committee (related terms: Reimbursement board, formulary panel) – a multidisciplinary group responsible for reviewing evidence and setting reimbursement prices for new therapies. Example: In many European health systems, the pricing committee evaluates cost-effectiveness reports before approving a price. Challenge: Balancing scientific rigor with political and budgetary pressures requires careful governance.

Pricing Model (related terms: Cost-plus, value-based) – a structured approach for determining the price of a product, incorporating factors such as development cost, therapeutic value, and market dynamics. Example: A value-based pricing model may set price proportional to the incremental health benefit achieved. Challenge: Quantifying value in monetary terms is inherently subjective.

Pricing Regulation (related terms: Price control, statutory limit) – governmental rules that dictate how drug prices may be set, adjusted, or reviewed. Example: Some jurisdictions require price reviews every two years to align with inflation. Challenge: Over-regulation can stifle market entry and reduce incentives for innovation.

Price-Volume Agreement (PVA) (related terms: Rebate, tiered discount) – a contract where the discount level varies according to the volume of product purchased, encouraging higher uptake. Example: A 10 % discount may apply up to 1,000 units, increasing to 20 % beyond that threshold. Challenge: Forecasting volumes accurately is essential to avoid unintended financial exposure.

Real-World Evidence (RWE) (related terms: Observational data, pragmatic trial) – data derived from routine clinical practice, used to supplement clinical trial evidence in pricing and reimbursement decisions. Example: RWE on long-term safety may be required to trigger full reimbursement after an initial conditional approval. Challenge: Data quality, completeness, and methodological rigor must meet HTA standards.

Reference Pricing (related terms: Price benchmarking, therapeutic class) – a system where a payer reimburses drugs based on a reference price set for a group of therapeutically similar products. Example: Patients may pay the difference if they choose a drug priced above the reference level. Challenge: Manufacturers may respond by withdrawing higher-priced products from the market.

Reimbursement Rate (related terms: Coverage level, payer contribution) – the proportion of a drug's price that a payer agrees to cover, often expressed as a percentage. Example: A 80 % reimbursement rate means the patient is responsible for the remaining 20 % of the cost. Challenge: Setting rates that reflect value while maintaining patient affordability is a delicate balance.

Reimbursement Submission (related terms: Dossier, pricing request) – the formal package of clinical,

economic, and pricing information presented to a payer for consideration of coverage. Example: The submission may include a health-economic model, budget impact analysis, and a proposed price. Challenge: Aligning submission timelines with regulatory approval dates is essential to avoid market delays.

Risk-Sharing Agreement (RSA) (related terms: MEA, outcome-based contract) – a contractual arrangement that links reimbursement to the achievement of specific clinical or financial outcomes, sharing risk between manufacturer and payer. Example: An RSA may provide a full refund if the drug fails to meet a pre-specified response rate. Challenge: Defining measurable outcomes and establishing data collection infrastructure are critical.

Scope of Indication (related terms: Label extension, therapeutic area) – the specific clinical condition(s) for which a drug is authorized and reimbursed. Example: A drug approved for metastatic breast cancer may later receive an expanded scope for early-stage disease. Challenge: Payers must reassess pricing when the therapeutic value changes with new indications.

Secret Discount (related terms: Confidential rebate, net price) – a reduction in price that is not disclosed publicly, often used to achieve competitive advantage without altering list price. Example: A secret discount of 12 % may be granted to a regional health authority in exchange for a formulary position. Challenge: Lack of visibility can distort market competition and hinder external reference pricing.

Segmentation Strategy (related terms: Market segmentation, differential pricing) – an approach that divides the market into distinct groups based on characteristics such as disease severity, payer type, or geographic region, allowing tailored pricing. Example: Premium pricing for a drug in high-income markets while offering tiered pricing for low-income countries. Challenge: Managing multiple pricing tiers increases administrative complexity and risk of parallel trade.

Sensitivity Analysis (related terms: Scenario testing, robustness check) – a technique used in economic modeling to assess how results change when key parameters are varied. Example: Varying the discount rate between 0 % and 5 % to test its impact on ICER. Challenge: Over-reliance on deterministic assumptions may overlook real-world variability.

Service Level Agreement (SLA) (related terms: Performance contract, quality guarantee) – a contract that defines the expected level of service, including delivery timelines and quality standards, often linked to reimbursement terms. Example: An SLA may require a manufacturer to supply a certain volume of product within a defined period. Challenge: Failure to meet SLA terms can trigger penalties or price adjustments.

Specialty Drug (related terms: High-cost therapy, biologic) – a class of high-price, often complex medicines that typically require special handling, administration, or monitoring. Example: Monoclonal antibodies for autoimmune diseases are classified as specialty drugs. Challenge: Their high budget impact necessitates rigorous HTA and innovative reimbursement models.

Stakeholder Engagement (related terms: Payer dialogue, patient advocacy) – the process of involving all relevant parties—payers, clinicians, patients, and regulators—in the development of pricing and reimbursement strategies. Example: Early engagement with HTA agencies can streamline evidence requirements. Challenge: Aligning divergent priorities requires transparent communication and negotiation

skills.

Standardized Pricing Framework (SPF) (related terms: Uniform methodology, pricing guideline) – a set of consistent principles and procedures used across a health system to determine drug prices. Example: An SPF may combine cost-plus and value-based components to derive a final price. Challenge: Ensuring the framework remains adaptable to emerging therapies is essential.

Strategic Price Setting (related terms: Market positioning, competitive analysis) – the deliberate process of choosing a price that reflects product value, market conditions, and long-term business objectives. Example: A launch price may be set lower to gain market share before incremental price increases. Challenge: Predicting competitor reactions and regulatory responses adds uncertainty.

Therapeutic Class (related terms: Drug category, indication group) – a group of medicines that share a common mechanism of action or therapeutic purpose, often used as a basis for reference pricing. Example: Statins constitute a therapeutic class for hypercholesterolemia. Challenge: Within-class heterogeneity can complicate price comparisons.

Therapeutic Value (related terms: Clinical benefit, incremental benefit) – the overall health benefit a drug provides relative to existing alternatives, encompassing efficacy, safety, and quality-of-life improvements. Example: A therapy that extends median survival by six months with minimal toxicity may be deemed high therapeutic value. Challenge: Quantifying value in monetary terms for pricing decisions remains contentious.

Tiered Pricing (related terms: Differential pricing, market segmentation) – a pricing structure where different price points are applied to distinct market segments, often based on income level or payer type. Example: High-income countries may pay a premium price while low-income nations receive a reduced rate. Challenge: Preventing parallel importation of lower-priced products into higher-price markets is a key concern.

Time-to-Market (related terms: Launch timeline, regulatory approval) – the interval between product development completion and the point at which the product becomes available to patients and reimbursed. Example: A shorter time-to-market can confer a competitive advantage for breakthrough therapies. Challenge: Accelerated pathways may reduce the evidence base, raising payer uncertainty.

Total Cost of Ownership (TCO) (related terms: Full cost accounting, lifecycle cost) – the comprehensive cost incurred by a payer over the entire lifespan of a therapy, including acquisition, administration, monitoring, and adverse-event management. Example: TCO for a gene therapy includes the upfront price plus long-term follow-up costs. Challenge: Capturing all cost components requires extensive data collection and modeling.

Value-Based Pricing (VBP) (related terms: Outcome-based pricing, cost-effectiveness) – a pricing strategy that sets the price of a drug according to the health outcomes it delivers, aligning price with therapeutic benefit. Example: A VBP model may price a drug at $50,000 per QALY gained. Challenge: Determining appropriate outcome measures and negotiating contracts that reflect them can be complex.

Variable Cost (related terms: Marginal cost, unit cost) – the cost that changes in proportion to the volume of

product produced or sold, such as manufacturing materials or distribution expenses. Example: The variable cost per vial of a biologic may decrease with economies of scale. Challenge: Accurately allocating variable costs across multiple indications is essential for pricing.

Volume-Based Discount (related terms: Price-volume agreement, tiered rebate) – a discount that increases as the quantity of product purchased rises, incentivizing higher utilization. Example: A 5 % discount may apply for purchases up to 500 units, with a 10 % discount beyond that level. Challenge: Forecasting volume accurately is necessary to avoid budget overruns or under-utilization.

Wholesale Acquisition Cost (WAC) (related terms: List price, ex-factory price) – the published price set by the manufacturer that represents the cost of a drug before discounts, rebates, or other price concessions. Example: The WAC is often used as a reference point for pricing negotiations. Challenge: WAC does not reflect actual transaction prices, limiting its usefulness for budgeting.

Willingness-to-Pay (WTP) (related terms: Threshold, utility valuation) – the maximum amount a payer or society is prepared to spend for a unit of health gain, such as a QALY. Example: A WTP of $100,000 per QALY may be applied in the United States. Challenge: Determining a socially acceptable WTP threshold involves ethical and political considerations.

World Health Organization (WHO) Model List of Essential Medicines (related terms: Essential drug list, global reference) – a list curated by the WHO that identifies medicines considered essential for a basic health system, influencing pricing negotiations and procurement. Example: Inclusion on the WHO list can facilitate lower pricing through pooled procurement. Challenge: The list may not keep pace with rapidly emerging high-cost therapies.

Zero-Sum Pricing (related terms: Price competition, market share) – a scenario where price reductions by one competitor are offset by price increases from another, resulting in no net gain for the overall market. Example: In a saturated market, a manufacturer may cut price to gain share, prompting rivals to raise theirs to maintain margins. Challenge: Such dynamics can destabilize pricing structures and complicate long-term planning.