

Certificato Professionale per la Creazione di una Strategia di Prezzi Sanitari (Italia)

## Regulatory Environment For Healthcare Pricing

**Accreditation** – related terms: Quality assurance, certification, compliance. A formal process by which a health-care organization demonstrates that it meets established standards set by an authorized body. In Italy, accreditation by Accredia or the Joint Commission International can affect pricing negotiations because accredited providers may command higher tariffs. Example: A private hospital obtains ISO 9001 accreditation and leverages this status to justify premium rates for elective surgeries. Challenges: Maintaining continuous compliance requires ongoing investment in staff training and documentation, and the impact on price perception varies across regions.

**Agency for Healthcare Research and Quality (AHRQ)** – related terms: Evidence-based policy, patient safety, research funding. A U.S. Federal agency that produces research and tools to improve health-care quality and cost-effectiveness. Although not an Italian body, AHRQ guidelines often influence European HTA assessments and pricing models. Example: AHRQ's "Hospital Compare" metrics are referenced by Italian payers when evaluating foreign-based providers seeking contracts. Challenges: Translating U.S. Data to the Italian context requires adjustment for regional practice patterns and reimbursement structures.

**Anti-Kickback Statute** – related terms: Fraud, conflict of interest, compliance. A U.S. Law prohibiting the exchange of remuneration for patient referrals. While Italy has its own anti-corruption statutes, the principle informs global best practices for pricing transparency. Example: A pharmaceutical company cannot offer rebates to physicians in exchange for prescribing its drugs, which would otherwise distort market prices. Challenges: Monitoring indirect incentives such as conference sponsorships demands robust audit mechanisms.

**Bundled Payments** – related terms: Episode-based reimbursement, global budget, cost containment. A payment model where a single, predetermined price covers all services related to a specific treatment episode (e.G., Hip replacement). In Italy, regional health authorities experiment with bundled payments to curb variability in surgical costs. Example: Lombardy's "All-In-One" bundle for knee arthroplasty includes pre-operative assessment, surgery, post-acute rehab, and follow-up visits. Challenges: Aligning incentives across multiple providers (hospital, surgeons, rehab centers) and managing outlier cases that exceed the bundle cost.

**Capitation** – related terms: Per-member-per-month (PMPM), risk adjustment, primary care networks. A fixed amount paid per enrolled patient to a provider for delivering a defined set of services over a period, regardless of utilization. Italian primary-care groups (GPs) may receive capitation fees adjusted for age, gender, and morbidity. Example: A regional health authority allocates €30 PMPM to a GP practice, covering preventive visits, chronic disease management, and minor acute care. Challenges: Providers must balance cost control with quality, as under-utilization can lead to penalties under performance-based contracts.

**Casemix** – related terms: DRG, resource intensity, patient classification. A system that groups patients with similar clinical characteristics and resource consumption, used to determine reimbursement levels. Italy

employs the “DRG-Italiano” (Diagnosis-Related Group) system, which influences tariff setting for hospitals. Example: Patients admitted for uncomplicated appendicitis are classified under DRG 123, receiving a standard reimbursement of €2,500. Challenges: Accurate coding is essential; upcoding or miscoding can trigger audits and financial penalties.

Clinical Guidelines – related terms: Best practice, standard of care, pathway. Evidence-based recommendations that define optimal diagnostic and therapeutic approaches for specific conditions. Adoption of national guidelines can affect pricing, as payers may reference them when negotiating service fees. Example: The Italian Ministry of Health’s guideline for diabetes care specifies quarterly HbA1c testing, influencing the reimbursable amount for laboratory services. Challenges: Updating guidelines to reflect emerging evidence requires coordination among professional societies and regulatory bodies.

Cost-Sharing – related terms: Co-payment, deductible, out-of-pocket expense. The portion of health-care costs that patients directly pay, designed to discourage over-utilization and share financial responsibility. In Italy, co-payment rates differ between essential and non-essential services. Example: Patients pay a €5 co-payment for a specialist visit not covered by the national health service, while the remaining €45 is reimbursed to the provider. Challenges: Excessive cost-sharing can create barriers to access, particularly for low-income populations, raising equity concerns.

DRG (Diagnosis-Related Group) – related terms: Casemix, tariff, case mix index. A classification system that assigns a fixed reimbursement amount to hospital admissions based on diagnosis, procedures performed, and severity. Italy’s DRG-Italiano system is updated annually by the Ministry of Health. Example: A patient admitted for acute myocardial infarction is placed in DRG 207, receiving a reimbursement of €7,800. Challenges: Hospitals must manage clinical pathways efficiently to stay within the DRG payment while maintaining quality standards.

E-Health – related terms: Telemedicine, digital health, health informatics. The use of information and communication technologies to support health-care delivery, data exchange, and patient engagement. Regulatory frameworks such as the EU’s Digital Health Strategy influence pricing for e-health services. Example: A teleconsultation platform receives a per-session tariff from regional health authorities, subject to data-privacy compliance under GDPR. Challenges: Ensuring interoperability, data security, and equitable reimbursement across digital and in-person services.

EU Medical Device Regulation (MDR) – related terms: CE marking, conformity assessment, post-market surveillance. A comprehensive regulatory framework governing the safety and performance of medical devices in the European Union, effective May 2021. Compliance affects pricing because manufacturers must incorporate cost of conformity assessment into product prices. Example: A new implantable cardiac device undergoes a Class III conformity assessment, increasing its market price by €1,200 to cover the certification process. Challenges: Lengthy approval timelines can delay market entry, impacting revenue projections and pricing strategies.

Fee-for-Service (FFS) – related terms: Activity-based reimbursement, volume-driven, price list. A traditional payment model where each service rendered is billed separately. In Italy, many outpatient services still follow FFS, leading to potential over-utilization. Example: A radiology department charges €120 per CT scan,

with each scan invoiced individually to the regional health service. Challenges: Encouraging efficiency while avoiding under-service requires monitoring of utilization patterns and implementing complementary value-based measures.

Health Technology Assessment (HTA) – related terms: Economic evaluation, cost-effectiveness, reimbursement dossier. A systematic evaluation of the medical, social, economic, and ethical implications of a health technology. Italy's HTA body (Agenzia Italiana del Farmaco – AIFA) provides recommendations that directly influence pricing negotiations. Example: An HTA report concludes that a new oncology drug offers an incremental cost-effectiveness ratio (ICER) of €45,000 per QALY, supporting a price cap of €25,000 per treatment course. Challenges: Balancing timely access with rigorous evidence appraisal, and managing stakeholder expectations.

Italian National Health Service (Servizio Sanitario Nazionale – SSN) – related terms: Universal coverage, regional autonomy, public payer. The publicly funded health-care system that provides universal access to essential services. Pricing decisions are largely made at the regional level, guided by national tariffs and policy directives. Example: The SSN reimburses a cataract surgery at €1,800, a rate negotiated between the Ministry of Health and regional authorities. Challenges: Regional disparities in resource allocation can lead to variable pricing structures across the country.

Joint Commission International (JCI) – related terms: Accreditation, quality standards, patient safety. An international organization that accredits health-care institutions based on rigorous standards. JCI accreditation can be leveraged by Italian hospitals to negotiate higher tariffs with private insurers. Example: A private clinic in Veneto obtains JCI accreditation and subsequently raises its price for cardiac surgery by 10% to reflect perceived quality. Challenges: Accreditation costs and ongoing compliance may strain smaller providers, limiting their ability to compete on price.

Legge 23/2003 (Italian Law on Pharmaceutical Prices) – related terms: Price control, reference pricing, reimbursement list. A legislative framework that sets criteria for determining the prices of pharmaceuticals covered by the SSN. Prices are often linked to reference prices from other EU countries. Example: The price of a new antihypertensive drug is set at 120% of the average price in France, Germany, and Spain, resulting in a list price of €15 per pack. Challenges: Manufacturers may delay market entry to avoid unfavorable reference pricing, affecting patient access.

Market Access – related terms: Reimbursement, pricing strategy, health-policy environment. The process of obtaining approval for a health product or service to be reimbursed and sold in a specific market. Successful market access in Italy requires alignment with HTA outcomes, pricing regulations, and regional negotiation. Example: A biotech firm conducts a value-dossier, secures a positive HTA opinion, and negotiates a risk-sharing agreement with the Lombardy health authority. Challenges: Navigating multiple regional payers, each with distinct budget constraints and evaluation criteria.

NICE (National Institute for Health and Care Excellence) – related terms: UK HTA, cost-effectiveness threshold, guidance. The UK body responsible for assessing the clinical and cost-effectiveness of health technologies. Although not Italian, NICE's methodology is often referenced by European HTA agencies, influencing pricing benchmarks. Example: An Italian manufacturer cites NICE's £30,000 per QALY threshold

when presenting cost-effectiveness data to AIFA. Challenges: Translating UK cost-utility results to the Italian cost structure requires adjustments for local practice patterns and price levels.

Obamacare (Affordable Care Act) – related terms: Health insurance exchanges, essential health benefits, price transparency. U.S. Legislation that introduced market-based reforms, including provisions for price transparency and value-based purchasing. Its concepts inspire similar reforms in the EU and Italy, such as the “Piano Nazionale della Trasparenza”. Example: Italian policymakers adopt a “price-shopping” portal for outpatient procedures, mirroring ACA’s transparency initiatives. Challenges: Adapting U.S. Policy mechanisms to the Italian universal coverage model while respecting regional autonomy.

Out-of-Pocket (OOP) Maximum – related terms: Catastrophic expense protection, cost-sharing cap, patient protection. A limit on the total amount a patient can spend on health-care services within a year. In Italy, OOP maximums apply mainly to private health-insurance plans, influencing the pricing of supplementary coverage. Example: A private insurer sets an OOP cap of €2,000 per year; any expenses beyond this are covered at 80% by the insurer. Challenges: Designing OOP caps that balance risk protection with premium affordability.

Pricing Transparency – related terms: Public price lists, cost disclosure, patient empowerment. The requirement that health-care providers disclose the prices of services and products to patients and payers. Italy’s “Codice di Deontologia Medica” encourages transparency, and recent EU directives reinforce this trend. Example: A hospital publishes a web-based tariff schedule for elective surgeries, enabling patients to compare costs across facilities. Challenges: Maintaining up-to-date price information, especially for bundled or variable services, and preventing price competition that could undermine quality.

Reimbursement – related terms: Tariff, payment schedule, claim. The process by which health-care providers receive payment from a payer (public or private) for services rendered. Italian reimbursement mechanisms include DRG tariffs for hospitals and fee-schedule rates for outpatient services. Example: After a patient’s discharge, the hospital submits a claim coded with DRG 301, receiving the pre-negotiated tariff of €4,600. Challenges: Delays in claim processing, disputes over coding accuracy, and the need for robust documentation.

Regulatory Impact Analysis (RIA) – related terms: Policy evaluation, cost-benefit analysis, stakeholder consultation. A systematic assessment of the potential effects of proposed regulations on the health-care market, including pricing implications. The Italian Ministry of Health conducts RIAs before implementing major pricing reforms. Example: An RIA predicts that lowering the price cap for generic drugs by 5% could save €200 million annually but may reduce manufacturer incentives for market entry. Challenges: Balancing economic efficiency with innovation incentives and patient access considerations.

Risk Adjustment – related terms: Morbidity weighting, actuarial value, capitation. A statistical method used to modify payments to health-care providers based on the health status of their enrolled populations, ensuring fair compensation for higher-risk patients. Italy’s regional health systems apply risk adjustment to capitation payments for GPs. Example: A GP practice serving an elderly population receives a 20% risk-adjustment factor, increasing its annual capitation budget accordingly. Challenges: Accurate data collection, preventing upcoding, and aligning incentives to avoid adverse selection.

**Tariff** – related terms: Price list, reimbursement rate, fee schedule. A predetermined amount paid for a specific health-care service, often set by a public authority or negotiated with insurers. Italian tariffs are published in the “Classificazione Tariffaria Nazionale”. Example: The tariff for a standard colonoscopy is €150, as listed in the national fee schedule. Challenges: Updating tariffs to reflect inflation, technological advances, and cost-containment pressures without compromising service quality.

**Value-Based Pricing (VBP)** – related terms: Outcome-linked payment, cost-effectiveness, risk-sharing. A pricing approach that ties the price of a health-care product or service to the value it delivers, measured in clinical outcomes or economic savings. Italy’s emerging VBP pilots for oncology drugs incorporate real-world effectiveness data. Example: A pharmaceutical company agrees to a VBP contract where the price of a targeted therapy is reduced by 15% if progression-free survival falls below a pre-specified threshold. Challenges: Defining appropriate outcome metrics, collecting reliable data, and negotiating risk-sharing terms acceptable to both payer and manufacturer.

**Virtual Care** – related terms: Telehealth, remote monitoring, digital consultation. Health-care services delivered through electronic communication platforms, allowing patients to receive clinical assessment without an in-person visit. Regulatory frameworks address licensure, data protection, and reimbursement. Example: A regional health authority reimburses €30 per virtual primary-care visit, provided the provider uses a certified telemedicine platform. Challenges: Ensuring equitable access for patients lacking digital infrastructure, and establishing quality standards for remote diagnoses.

**Wholesale Price Index (WPI)** – related terms: Inflation measure, price adjustment, cost escalation. An economic indicator that tracks changes in the price of goods at the wholesale level, often used to adjust health-care tariffs for inflation. Italian health authorities may index certain drug prices to the WPI. Example: A 2% increase in the WPI leads to a proportional rise in the reimbursement rate for generic antibiotics. Challenges: Lag in data reporting and the potential mismatch between wholesale price movements and actual service cost changes.

**Zero-Sum Pricing** – related terms: Price competition, market share, margin pressure. A market situation where any price gain by one provider is offset by a corresponding loss by another, resulting in no net increase in overall revenue. In highly competitive Italian regions, hospitals may engage in zero-sum pricing for elective procedures. Example: Two hospitals in Sicily reduce their knee-replacement tariffs by 5% simultaneously to attract patients, without increasing total market revenue. Challenges: Sustaining profitability while competing on price, and avoiding a race to the bottom that could compromise care quality.

**Annual Review Committee (Comitato di Revisione Annuale)** – related terms: Price revision, stakeholder meeting, budget alignment. A body convened each year by regional health authorities to assess and adjust tariffs, considering inflation, utilization trends, and budget constraints. Example: The Tuscany Annual Review Committee approves a 3% increase in hospital DRG tariffs for the upcoming fiscal year. Challenges: Balancing diverse stakeholder interests, ensuring transparency, and preventing politicized pricing decisions.

**Benefit-Risk Assessment** – related terms: Safety profile, efficacy data, regulatory decision. A systematic evaluation of the therapeutic advantages of a health product relative to its potential risks. Positive

benefit-risk outcomes can support premium pricing for innovative therapies. Example: A new biologic demonstrates a high benefit-risk ratio, justifying a price of €45,000 per treatment course under a conditional reimbursement scheme. Challenges: Managing post-marketing safety data and addressing emerging adverse events that may alter pricing agreements.

Cost-Effectiveness Threshold – related terms: Willingness-to-pay, ICER, health-technology assessment. The maximum amount a payer is willing to spend per unit of health gain (e.g., Per quality-adjusted life year). Italy does not have a formally legislated threshold, but AIFA often references €30,000–€50,000 per QALY in its deliberations. Example: A drug with an ICER of €40,000/QALY may be accepted for reimbursement, whereas one with €70,000/QALY may be rejected or subject to price reduction. Challenges: Determining an appropriate threshold that reflects societal values, budget impact, and equity considerations.

Data-Driven Pricing – related terms: Analytics, real-world evidence, dynamic pricing. The use of large-scale health data to inform price setting, adjusting tariffs based on utilization patterns, outcomes, and cost trends. Italian health regions are piloting data-driven models for chronic-disease management programs. Example: An analytics platform identifies that patients with uncontrolled diabetes generate higher downstream costs; the region implements a higher tariff for intensive case-management services. Challenges: Ensuring data quality, protecting patient privacy, and integrating analytics into existing reimbursement workflows.

Economic Evaluation – related terms: Cost-utility analysis, budget impact analysis, comparative effectiveness. A methodological approach that compares the costs and outcomes of alternative health interventions. Results are integral to HTA reports and pricing negotiations. Example: A cost-utility analysis shows that a new vaccine yields 0.8 QALYs at an incremental cost of €6,000, resulting in an ICER of €7,500/QALY, supporting a favorable price. Challenges: Selecting appropriate comparators, handling uncertainty, and communicating findings to non-technical stakeholders.

Fee Schedule – related terms: Tariff list, reimbursement catalog, negotiated rates. A comprehensive list of prices for a range of health-care services, often established by a public payer or insurer. Italy's national fee schedule is periodically updated to reflect clinical practice changes. Example: The fee schedule assigns €50 to a basic ophthalmology consultation and €120 to a comprehensive eye examination. Challenges: Keeping the schedule current, accommodating regional variations, and preventing price erosion in competitive markets.

Generic Substitution – related terms: Bioequivalence, price competition, pharmacy policy. The practice of dispensing a lower-cost generic equivalent of a brand-name drug. Italian law mandates generic substitution unless the prescriber explicitly prohibits it, influencing drug pricing dynamics. Example: A patient receiving a brand-name antihypertensive is switched to a generic version, saving €15 per month. Challenges: Ensuring therapeutic equivalence, managing patient and physician acceptance, and monitoring market share shifts.

Health Care Cost Containment – related terms: Budgetary restraint, efficiency measures, spending caps. Strategies employed by governments and payers to limit the growth of health-care expenditures while maintaining quality. Measures include tariff reductions, utilization reviews, and promotion of value-based purchasing. Example: A regional authority implements a 2% annual cap on hospital spending, prompting providers to adopt efficiency protocols. Challenges: Avoiding unintended consequences such as service

rationing or reduced access to innovative therapies.

**Incentive-Based Contracting** – related terms: Pay-for-performance, quality bonuses, shared savings. Contracts that link provider remuneration to the achievement of predefined performance metrics, encouraging higher quality and efficiency. Italy's "Contratti di Qualità" incorporate incentive payments for meeting outcome targets. Example: A hospital receives a 5% bonus on its DRG payments if its surgical site infection rate falls below 1%. Challenges: Defining measurable, fair indicators and preventing gaming of metrics.

**International Reference Pricing (IRP)** – related terms: Cross-border price comparison, price benchmarking, price regulation. A method where a country's drug price is set based on the price of the same product in a basket of reference countries. Italy applies IRP for many pharmaceuticals, using a weighted average of EU member states. Example: The price of a new oncology drug is capped at 120% of the average price in France, Germany, and Spain. Challenges: Currency fluctuations, differences in market size, and potential delays in price updates.

**Joint Procurement** – related terms: Collaborative buying, economies of scale, tendering. A purchasing arrangement where multiple health authorities combine demand to negotiate better prices from suppliers. Italian regions occasionally engage in joint procurement of medical devices. Example: Five regions jointly issue a tender for MRI scanners, achieving a 15% discount compared to individual purchases. Challenges: Coordinating specifications, aligning timelines, and managing post-procurement logistics.

**Key Performance Indicator (KPI)** – related terms: Metric, performance measurement, benchmarking. A quantifiable measure used to evaluate the success of an organization in achieving its objectives. In pricing, KPIs may include average cost per episode, reimbursement cycle time, or price variance. Example: A hospital tracks the KPI "average DRG cost deviation" to monitor tariff compliance. Challenges: Selecting relevant KPIs, ensuring data accuracy, and avoiding over-emphasis on metrics that do not reflect patient outcomes.

**Legislative Decree (Decreto Legislativo)** – related terms: Statutory instrument, regulatory framework, implementation law. A legal instrument in Italy that translates EU directives into national law, often detailing specific pricing rules for health services. Example: Decreto Legislativo 219/2006 outlines the methodology for calculating pharmaceutical price reductions. Challenges: Interpreting complex legal language and aligning operational processes with legislative requirements.

**Market Exclusivity** – related terms: Patent protection, data exclusivity, monopoly pricing. A period during which a new drug or device enjoys protection from generic competition, allowing the holder to set higher prices. In Italy, market exclusivity can be granted for up to eight years for innovative medicines. Example: A novel biologic receives eight years of market exclusivity, during which its price is not subject to reference pricing. Challenges: Balancing incentives for innovation with the need for affordable access once exclusivity expires.

**Negotiated Discount** – related terms: Rebate, price concession, contract clause. A reduction in the list price of a product or service agreed upon between a payer and a supplier, often tied to volume commitments or performance outcomes. Example: A regional health authority secures a 10% negotiated discount on a class of antibiotics in exchange for a minimum purchase volume. Challenges: Monitoring compliance, preventing

hidden rebate structures, and ensuring discounts do not compromise supply continuity.

**Outcome-Based Contract** – related terms: Performance-linked payment, risk-sharing, value-based agreement. A contractual arrangement where reimbursement is contingent upon achieving specific health outcomes. These contracts aim to align provider incentives with patient benefits. Example: A pharmaceutical company agrees to refund 20% of the drug cost if patients do not achieve a predefined reduction in HbA1c levels. Challenges: Defining robust, measurable outcomes, collecting reliable data, and managing financial risk for both parties.

**Pharmaceutical Benefit Scheme (Fondo per il Farmaco)** – related terms: Drug reimbursement, formulary, price negotiation. A national fund that supports the reimbursement of essential medicines, often negotiating prices on behalf of the SSN. Example: The fund negotiates a price for a new antiviral, resulting in a 30% discount from the manufacturer's list price. Challenges: Limited budget allocation, balancing therapeutic innovation with cost containment, and ensuring equitable access across regions.

**Price Cap** – related terms: Maximum price, ceiling, regulatory ceiling. A limit imposed by a regulator on the highest price that can be charged for a health-care product or service. Italy utilizes price caps for certain high-cost drugs to protect the budget. Example: A price cap of €5,000 is set for a rare-disease therapy, regardless of the manufacturer's suggested price. Challenges: Determining appropriate cap levels that reflect value without discouraging market entry.

**Quality Adjusted Life Year (QALY)** – related terms: Health utility, cost-utility analysis, outcome measure. A metric that combines length of life with quality of health, used to assess the value of medical interventions. QALYs are central to cost-effectiveness calculations that inform pricing decisions. Example: An intervention provides 0.5 QALYs at an incremental cost of €10,000, yielding an ICER of €20,000 per QALY. Challenges: Valuing health states across diverse populations and addressing ethical concerns about assigning monetary values to life.

**Risk-Sharing Agreement (RSA)** – related terms: Performance-based contract, outcome-linked reimbursement, financial risk. A contractual mechanism where the payer and manufacturer share the financial risk associated with the therapeutic performance of a product. RSA can include refunds, price adjustments, or volume guarantees. Example: A risk-sharing agreement stipulates that the manufacturer will provide a 25% price rebate if the drug's real-world effectiveness falls below 70% of the clinical trial results. Challenges: Establishing transparent measurement criteria, handling data lag, and negotiating equitable risk distribution.

**Service Level Agreement (SLA)** – related terms: Contract terms, performance standards, compliance. A formal agreement that defines the expected level of service, including response times, availability, and quality standards. In health-care pricing, SLAs may be attached to outsourced services such as laboratory testing. Example: A laboratory contract includes an SLA guaranteeing 95% of test results delivered within 24 hours. Challenges: Monitoring compliance, imposing penalties for breaches, and aligning SLAs with clinical priorities.

**Tariff Revision** – related terms: Price update, indexation, fiscal year adjustment. The periodic process of reviewing and updating tariffs to reflect changes in costs, inflation, and policy objectives. In Italy, tariff

revisions often occur annually or biennially. Example: The 2025 tariff revision raises the price for cardiac catheterization by 4% to account for increased equipment costs. Challenges: Balancing timely updates with budgetary constraints and ensuring stakeholder consensus.

Unified Health Pricing Framework (UHPF) – related terms: National pricing policy, standardization, cross-regional alignment. A conceptual model aiming to harmonize pricing rules across all Italian regions, reducing disparities and promoting transparency. While not yet fully implemented, the UHPF proposes common methodology for DRG tariffs and drug price negotiations. Example: Under the UHPF, all regions adopt a unified formula for calculating hospital DRG rates based on average national cost data. Challenges: Reconciling regional autonomy with national standardization, and managing transitional costs.

Value-Based Insurance Design (VBID) – related terms: Cost-sharing alignment, incentive design, clinical benefit. An insurance strategy that reduces patient cost-sharing for high-value services while increasing it for low-value ones, encouraging appropriate utilization. Italian insurers are experimenting with VBID for chronic-disease medications. Example: A VBID plan eliminates co-payment for statins shown to reduce cardiovascular events, while maintaining standard co-payment for less effective lipid-lowering agents. Challenges: Identifying high-value services, communicating plan changes to beneficiaries, and measuring impact on health outcomes.

Wholesale Acquisition Cost (WAC) – related terms: List price, net price, discount. The manufacturer's list price for a drug sold to wholesalers, before rebates or discounts are applied. WAC serves as a reference point for pricing negotiations in Italy. Example: The WAC of a new oncology drug is €2,500 per vial; after a 20% rebate, the net price to the SSN becomes €2,000. Challenges: Lack of transparency about actual transaction prices and variability in rebate structures across suppliers.

Zero-Based Budgeting (ZBB) – related terms: Incremental budgeting, cost justification, resource allocation. A budgeting approach where each expense must be justified from scratch, rather than based on previous spending levels. Some Italian health regions adopt ZBB for allocating funds to high-cost services. Example: A department submits a ZBB proposal to fund a new robotic surgery program, detailing expected patient volume and cost savings. Challenges: Time-intensive preparation, potential under-funding of essential services, and resistance from stakeholders accustomed to incremental budgeting.