Professional Certificate in Medical Device Management

Health Economics and Reimbursement for Medical Devices

Health Economics and Reimbursement Glossary

A

1. Adverse Selection: In health economics and reimbursement, adverse selection refers to the situation where individuals with higher risks or greater healthcare needs are more likely to purchase or seek coverage for health insurance. This phenomenon can lead to higher costs for insurers and may result in market instability.

2. Agency for Healthcare Research and Quality (AHRQ): AHRQ is a federal agency in the United States that conducts research to improve the quality, safety, efficiency, and effectiveness of healthcare. It plays a crucial role in generating evidence-based information to inform health policy and decision-making.

3. Alternative Payment Models (APMs): APMs are reimbursement approaches that incentivize healthcare providers to deliver cost-effective, high-quality care. Examples of APMs include accountable care organizations (ACOs) and bundled payment arrangements.

4. Approval Pathway: The approval pathway refers to the regulatory process that medical devices must undergo to gain market authorization for commercial distribution. Different countries have varying pathways, such as the FDA's premarket approval (PMA) process in the United States.

5. Average Wholesale Price (AWP): AWP is a pricing benchmark used in healthcare to establish reimbursement rates for pharmaceuticals and medical devices. It represents the average price at which wholesalers sell products to retailers.

B

6. Benchmarking: Benchmarking is a strategic management tool that involves comparing an organization's performance metrics, practices, or processes against industry standards or best practices. In healthcare, benchmarking can help identify areas for improvement in reimbursement strategies.

7. Bundled Payments: Bundled payments involve a single payment for a defined episode of care, encompassing all services provided by multiple healthcare providers. This reimbursement model aims to promote care coordination, cost containment, and quality improvement.

8. Business Impact Analysis (BIA): BIA is a process that evaluates the potential consequences of disruptions to an organization's operations. In the context of medical device management, conducting a BIA can help assess the financial implications of reimbursement changes or market shifts.

C

9. Capitation: Capitation is a payment arrangement in healthcare where providers receive a fixed amount per patient per period, regardless of the services rendered. This model incentivizes providers to deliver efficient and cost-effective care while managing patient populations.

10. Cash Flow: Cash flow refers to the movement of money in and out of a business over a specific period. For medical device companies, understanding cash flow is crucial for managing operational expenses, investment decisions, and navigating reimbursement challenges.

11. Clinical Evidence: Clinical evidence encompasses data from studies, trials, and real-world experiences that demonstrate the safety, efficacy, and clinical benefits of a medical device. Strong clinical evidence is essential for obtaining reimbursement and market acceptance.

12. Clinical Utility: Clinical utility refers to the extent to which a medical device improves patient outcomes, quality of life, or healthcare delivery. Demonstrating the clinical utility of a device is critical for securing reimbursement and adoption by payers and providers.

D

13. Diagnostic Related Groups (DRGs): DRGs are a payment system used by Medicare and other insurers to categorize hospital inpatient stays into groups based on similar clinical conditions and treatment. Each DRG has a predetermined payment amount, influencing hospital reimbursement.

14. Direct Costs: Direct costs are expenses directly attributable to the production, distribution, or sale of a product or service. In the context of medical devices, direct costs may include materials, manufacturing, and regulatory compliance costs that impact pricing and reimbursement.

15. Drug-Eluting Stent (DES): A DES is a medical device used in coronary artery disease treatment, designed to release medication to prevent restenosis (re-narrowing of blood vessels). Reimbursement considerations for DES may involve comparative effectiveness, cost-effectiveness, and coverage policies.

E

16. Economic Evaluation: Economic evaluation involves assessing the costs and outcomes of healthcare interventions to inform resource allocation decisions. Common methods include cost-effectiveness analysis, cost-utility analysis, and budget impact analysis in the context of medical device reimbursement.

17. Episode of Care: An episode of care refers to a sequence of healthcare services provided to treat a specific health condition or patient need. Bundled payment models aim to align reimbursement with the entire episode of care, promoting value-based healthcare delivery.

18. Evidence-Based Medicine (EBM): EBM is an approach to clinical decision-making that integrates the best available evidence from research, clinical expertise, and patient preferences. Manufacturers of medical devices must generate robust evidence to support product value and reimbursement claims.

F

19. Fee-for-Service: Fee-for-service is a traditional payment model in healthcare where providers are reimbursed based on the volume of services delivered. This model has been associated with overutilization, lack of care coordination, and rising costs, prompting a shift towards value-based reimbursement.

20. Food and Drug Administration (FDA): The FDA is a regulatory agency in the United States responsible for protecting public health by regulating food, drugs, biologics, medical devices, and other products. Medical device manufacturers must adhere to FDA requirements for market approval and reimbursement.

21. Formulary: A formulary is a list of prescription drugs or medical devices approved for use by a healthcare provider, insurer, or pharmacy benefit manager. Inclusion on a formulary can impact patient access, reimbursement, and market uptake for medical devices.

G

22. Global Budgeting: Global budgeting is a reimbursement approach that sets a fixed total amount for healthcare spending within a defined population or region. This model aims to control costs, promote efficiency, and encourage healthcare providers to manage resources effectively.

23. Health Economics: Health economics is a branch of economics that examines how healthcare resources are allocated, utilized, and distributed to optimize health outcomes. Understanding health economics is essential for medical device managers to navigate reimbursement challenges and market dynamics.

24. Health Technology Assessment (HTA): HTA is a multidisciplinary process that evaluates the clinical, economic, social, and ethical implications of healthcare technologies, including medical devices. HTA plays a crucial role in informing reimbursement decisions, coverage policies, and technology adoption.

25. Healthcare Utilization: Healthcare utilization refers to the use of healthcare services by individuals or populations, including hospital visits, physician consultations, diagnostic tests, and medical procedures. Analyzing healthcare utilization patterns can provide insights into reimbursement trends and healthcare delivery efficiency.

I

26. Inpatient Prospective Payment System (IPPS): IPPS is a reimbursement system used by Medicare to pay hospitals for inpatient services based on diagnosis-related groups. Understanding IPPS is essential for medical device managers to navigate hospital reimbursement and market access strategies.

27. International Classification of Diseases (ICD): ICD is a standardized system for classifying and coding diseases, injuries, and health conditions for statistical and billing purposes. Medical devices may be linked to specific ICD codes for reimbursement and coverage purposes.

28. Investment Decisions: Investment decisions involve allocating financial resources to projects, initiatives, or assets that are expected to generate returns or strategic value. Medical device managers must consider reimbursement trends, market dynamics, and regulatory factors when making investment decisions.

J

29. Joint Commission: The Joint Commission is an independent, nonprofit organization that accredits and certifies healthcare organizations and programs in the United States. Compliance with Joint Commission standards can impact reimbursement, quality metrics, and patient safety in healthcare settings.

K

30. Key Performance Indicators (KPIs): KPIs are measurable metrics that reflect an organization's performance in achieving strategic objectives. Medical device managers may use KPIs related to sales, reimbursement, market share, and customer satisfaction to track business success and inform decision-making.

L

31. Life Cycle Costing: Life cycle costing involves assessing the total costs of a product or asset over its entire life span, including acquisition, operation, maintenance, and disposal. Understanding life cycle costs is crucial for pricing strategies, reimbursement negotiations, and budget planning in medical device management.

32. Lump-Sum Payments: Lump-sum payments are fixed, one-time reimbursements made for a specific healthcare service, episode of care, or population. This reimbursement model can provide financial predictability for providers but may require careful cost management and risk assessment.

M

33. Market Access: Market access refers to the process of ensuring that a medical device is available, reimbursed, and adopted by healthcare providers, payers, and patients. Effective market access strategies involve navigating regulatory pathways, reimbursement policies, and stakeholder relationships.

34. Market Dynamics: Market dynamics encompass the forces and factors that influence supply, demand, pricing, and competition within a market. Medical device managers must monitor market dynamics, such as reimbursement trends, technology advancements, and competitor activities, to make informed decisions.

35. Medicaid: Medicaid is a joint federal and state program in the United States that provides health coverage to eligible low-income individuals and families. Understanding Medicaid policies, reimbursement rates, and patient populations is essential for medical device companies targeting this market.

36. Medicare: Medicare is a federal health insurance program in the United States that primarily covers individuals aged 65 and older, as well as certain younger people with disabilities. Medical device managers must navigate Medicare reimbursement rules, coverage policies, and payment systems to access this market.

37. Medical Device Reimbursement: Medical device reimbursement encompasses the processes and mechanisms by which healthcare payers, such as insurers and government agencies, provide payment for medical devices. Understanding reimbursement policies, codes, and coverage criteria is essential for market

success.

38. Medicare Coverage Pathway: The Medicare coverage pathway outlines the steps and requirements for determining whether a medical device is eligible for coverage under Medicare. Manufacturers must navigate the pathway, which may involve evidence generation, coding, and reimbursement negotiations, to access this market.

39. Medicare Severity-Diagnosis Related Groups (MS-DRGs): MS-DRGs are a payment methodology used by Medicare to classify and reimburse hospital inpatient stays based on clinical severity and resource utilization. Medical device managers must understand MS-DRG coding and reimbursement implications for product adoption.

40. Monetary Policy: Monetary policy refers to the actions taken by a central bank to manage the supply of money, interest rates, and economic stability. Changes in monetary policy can impact healthcare spending, reimbursement rates, and investment decisions in the medical device industry.

N

41. National Institute for Health and Care Excellence (NICE): NICE is an independent organization in the United Kingdom that provides guidance on healthcare technologies, including medical devices. Manufacturers may seek NICE approval to enhance market access, reimbursement, and technology adoption.

42. Net Present Value (NPV): NPV is a financial metric that calculates the present value of future cash flows generated by an investment, adjusted for the time value of money. Medical device managers use NPV analysis to assess the profitability and viability of reimbursement strategies and market opportunities.

43. New Technology Add-On Payment (NTAP): NTAP is a payment mechanism used by Medicare to provide additional reimbursement for high-cost, innovative technologies that meet certain criteria. Medical devices eligible for NTAP may receive supplemental payments to support market adoption and access.

O

44. Outcomes-Based Reimbursement: Outcomes-based reimbursement ties payment for healthcare services or products to achieved outcomes, such as improved patient health or cost savings. Medical device manufacturers may engage in outcomes-based contracts with payers to align incentives and demonstrate value.

45. Out-of-Pocket Costs: Out-of-pocket costs are expenses that individuals pay directly for healthcare services or products, not covered by insurance or other third-party payers. Understanding out-of-pocket costs is essential for medical device managers to assess patient affordability and market demand.

46. Overhead Costs: Overhead costs are ongoing expenses required to operate a business but not directly attributable to specific products or services. Medical device managers must consider overhead costs, such as administrative, marketing, and facility expenses, when pricing products and negotiating reimbursement.

P

47. Patient-Centered Outcomes Research Institute (PCORI): PCORI is a nonprofit organization in the United States that funds research to inform healthcare decisions based on patient preferences, outcomes, and comparative effectiveness. Medical device manufacturers may use PCORI evidence to support reimbursement and market access.

48. Performance-Based Reimbursement: Performance-based reimbursement links payment for healthcare services or products to predefined performance metrics, such as quality measures or patient outcomes. Medical device companies may engage in performance-based contracts with payers to demonstrate value and improve care delivery.

49. Post-Market Surveillance: Post-market surveillance involves monitoring and evaluating the safety, effectiveness, and performance of medical devices after commercialization. Manufacturers must conduct post-market surveillance to comply with regulatory requirements, address adverse events, and support reimbursement claims.

50. Pre-Market Approval (PMA): PMA is a regulatory pathway used by the FDA to evaluate and approve high-risk medical devices before they can be marketed in the United States. Medical device managers must navigate the PMA process, which includes clinical data submission, to obtain market authorization and reimbursement.

51. Price Transparency: Price transparency refers to the disclosure of healthcare costs, prices, and reimbursement rates to patients, providers, and payers. Increasing price transparency in the medical device industry can enhance market competition, consumer choice, and value-based decision-making.

52. Private Payers: Private payers are non-governmental insurers or health plans that provide coverage for healthcare services, including medical devices. Understanding private payer policies, reimbursement rates, and coverage criteria is essential for market access and product adoption strategies.

Q

53. Quality Metrics: Quality metrics are measurable indicators that assess the effectiveness, safety, and efficiency of healthcare services or products. Medical device managers may track quality metrics related to patient outcomes, adverse events, and compliance to demonstrate value and support reimbursement claims.

R

54. Reimbursement: Reimbursement refers to the payment or compensation provided to healthcare providers, facilities, or manufacturers for delivering medical services or products. Understanding reimbursement mechanisms, coding requirements, and coverage policies is essential for market success in the medical device industry.

55. Reimbursement Challenges: Reimbursement challenges encompass the obstacles and complexities faced by medical device manufacturers in securing payment for their products. Challenges may include coding

issues, coverage denials, pricing pressures, and regulatory changes that impact market access and profitability.

56. Reimbursement Codes: Reimbursement codes are alphanumeric identifiers used to bill and track healthcare services or products for reimbursement purposes. Medical device managers must understand coding systems, such as CPT, HCPCS, and ICD, to ensure accurate billing, compliance, and reimbursement for their products.

57. Relative Value Units (RVUs): RVUs are metrics used in the Medicare physician fee schedule to quantify the resources required to provide healthcare services. Understanding RVUs is essential for medical device managers to assess reimbursement rates, negotiate payment contracts, and optimize market access strategies.

58. Resource-Based Relative Value Scale (RBRVS): RBRVS is a payment methodology used by Medicare to determine reimbursement rates for physician services based on the relative value of work, practice expenses, and malpractice costs. Medical device managers must consider RBRVS when pricing products and negotiating contracts with providers.

59. Return on Investment (ROI): ROI is a financial metric that calculates the profitability of an investment by comparing the gains or benefits generated against the costs incurred. Medical device managers use ROI analysis to evaluate reimbursement strategies, market opportunities, and resource allocations for optimal returns.

60. Risk Adjustment: Risk adjustment is a process used in healthcare reimbursement to account for differences in patient populations' health status or complexity. Adjusting payments based on risk factors helps ensure fair and accurate reimbursement for providers and incentivizes high-quality care delivery.

S

61. Stakeholder Engagement: Stakeholder engagement involves involving individuals, organizations, or groups with a vested interest in the outcomes or decisions related to a medical device. Effective stakeholder engagement can enhance market access, reimbursement negotiations, and product adoption strategies.

62. Strategic Pricing: Strategic pricing involves setting prices for medical devices based on market dynamics, competition, value proposition, and reimbursement considerations. Medical device managers must develop pricing strategies that align with reimbursement rates, cost structures, and customer expectations to maximize profitability.

63. Supply Chain Management: Supply chain management encompasses the planning, sourcing, manufacturing, and distribution of products, including medical devices. Effective supply chain management is critical for optimizing costs, quality, and market access in the medical device industry.

T

64. Technology Assessment: Technology assessment involves evaluating the clinical, economic, and social implications of healthcare technologies, including medical devices. Manufacturers must conduct technology

assessments to demonstrate value, support reimbursement claims, and navigate market access challenges.

65. Telehealth Reimbursement: Telehealth reimbursement refers to the payment mechanisms for delivering healthcare services remotely using telecommunications technology. Understanding telehealth reimbursement policies, coding requirements, and coverage criteria is essential for medical device companies offering telehealth solutions.

66. Total Cost of Ownership (TCO): TCO is a financial metric that calculates the overall costs associated with owning, operating, and maintaining a product or asset over its life cycle. Medical device managers use TCO analysis to assess profitability, pricing strategies, and reimbursement negotiations for optimal decision-making.

67. Triple Aim: The Triple Aim is a framework developed by the Institute for Healthcare Improvement that aims to improve healthcare quality, enhance patient experience, and reduce costs simultaneously. Medical device managers may align product strategies with the Triple Aim goals to drive value-based care delivery and reimbursement.

U

68. Unbundled Payments: Unbundled payments involve separate reimbursement for individual healthcare services or components within an episode of care. This payment model allows providers to bill for specific procedures or interventions, influencing revenue generation, cost transparency, and care delivery efficiency.

69