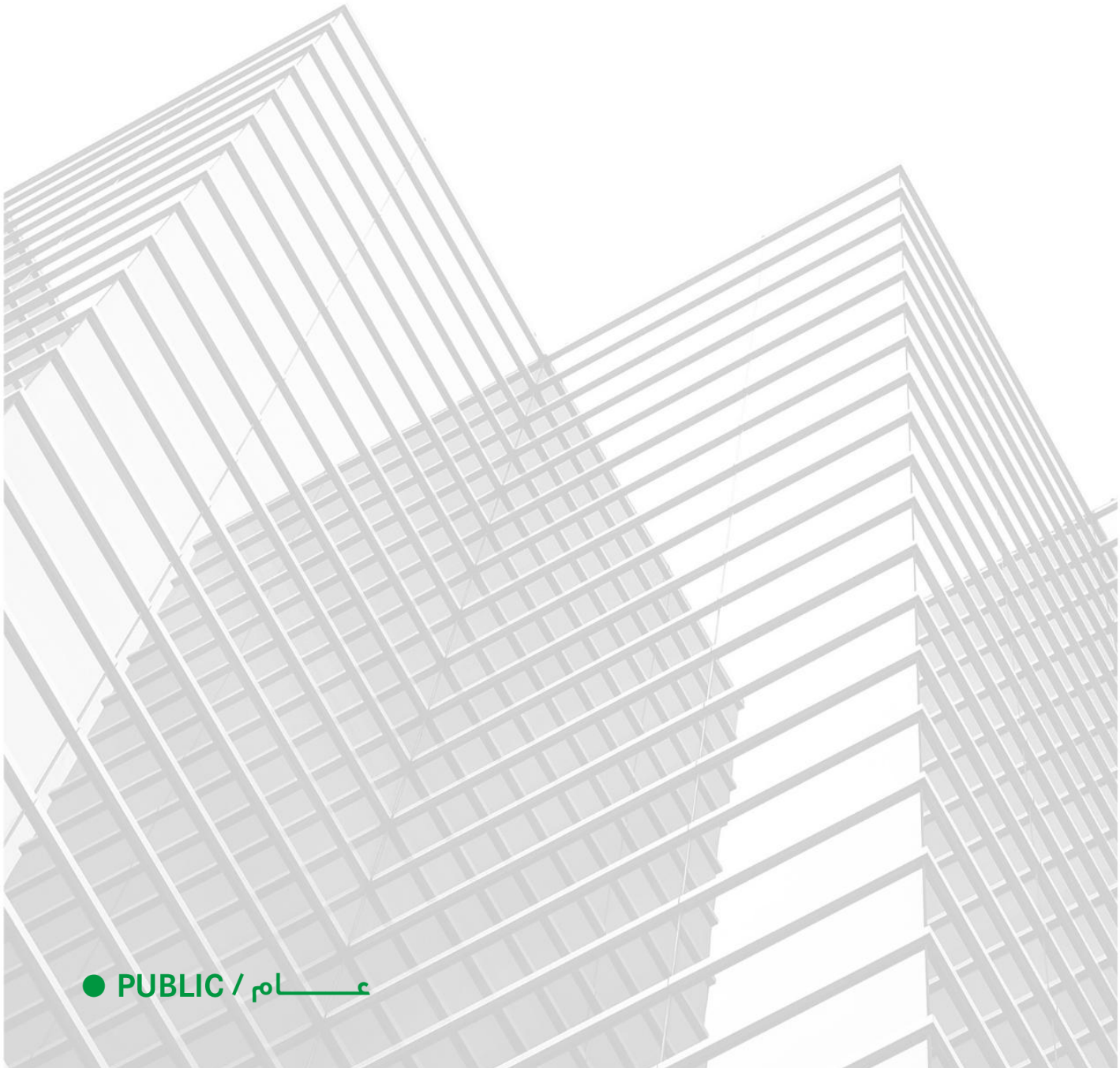
دائـــــرة الـصـــحـــة
DEPARTMENT OF HEALTH

Durable Medical Equipment Policy



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1. Policy Purpose and Brief

1.1 The Durable Medical Equipment (DME) Policy aims to ensure equitable access to medically necessary, high-quality DME for Abu Dhabi residents, enhancing patient safety, functional independence, and quality of life while preventing hospitalization or institutionalization.

1.2 It establishes a regulatory framework for DME reimbursement, prescription, and management, aligning with UAE Health Insurance Laws and MOHAP regulations.

1.3 The policy mitigates risks such as inappropriate DME use, non-compliance with international standards, and financial inefficiencies in healthcare delivery.

1.4 Expected Results:

1.4.1 Improved patient outcomes through timely access to DME.

1.4.2 Enhanced compliance with FDA, EMA, and MOHAP standards.

1.4.3 Reduced healthcare costs via cost-effective DME utilization.

1.4.4 Strengthened patient safety and care quality through robust monitoring.

1.4.5 This policy supports DoH's priorities of patient-centered care and health system sustainability, with specific provisions for respiratory DME in Appendix 1 and Appendix 2.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	ADHTA	Abu Dhabi Health technology assessment
2.2	Activities of Daily Living (ADL)	Basic tasks such as eating, bathing, dressing, and mobility.
2.3	ASR	Approved Supplier Register
2.4	Bilevel Positive Airway Pressure (BiPAP)	A respiratory device for complex respiratory needs (see Appendix 2).
2.5	CAPA	Corrective and Preventive Action
2.6	Continuous Positive Airway Pressure (CPAP)	A respiratory device for OSA (see Appendix 2).
2.7	Durable Medical Equipment (DME)	A device that is specifically designed for long-term use to assist patients with medical conditions or disabilities in their daily lives, primarily in a home setting. DME is often prescribed for chronic conditions and includes items like wheelchairs, oxygen tanks, and hospital beds intended for use over an extended period. It is approved by an internationally recognized regulatory agency (e.g., FDA, EMA, MOHAP). • Enables tasks otherwise unachievable due to a medical condition. • Is life-sustaining or medically/functionally necessary. • Prevents frequent hospitalization or ER visits. • Withstands repeated use. • Serves a medical purpose, not convenience. • Is generally not useful without illness/injury. • Is suitable for home use, transportable for ADLs. • Is prescribed by a specialist per insurance benefits. • Includes orthotics, prostheses, wheelchairs, respiratory devices (see Appendix 2), oxygen concentrators, nebulizers, etc.

		• Excludes disposable supplies (e.g., catheters, bandages), non-durable equipment, or devices used outside the UAE.
2.8	Department of Health (DoH)	The regulative body of the Healthcare Sector in the Emirate of Abu Dhabi, Established based on law No. (10) of 2018.
2.9	EMA	European Medicines Agency
2.10	FDA	Food and Drug Administration
2.11	FSN	Field Safety Notice
2.12	HCPCS	Healthcare Common Procedure Coding System
2.13	High-Frequency Chest Wall Oscillation (HFCWO)	A device for mucus clearance (see Appendix 2).
2.14	ICD	International Classification of Diseases
2.15	ICF	International Classification of Functioning
2.16	IFU	Instructions for Use
2.17	ISO	International Organization for Standardization
2.18	K-Level	Medicare Functional Classification Level
2.19	MDR	Medical Device Regulation
2.20	Ministry of Health and Prevention (MOHAP)	UAE regulatory authority for medical devices.
2.21	MRN	Medical Record Number
2.22	Non-standard/ customized DME	Medical equipment with convenience features tailored to a specific patient's medical needs.
2.23	O&P	Orthotics and Prosthetics
2.24	OPUS	Orthotics and Prosthetics Users Survey
2.25	PMS	Post-Market Surveillance
2.26	QMS	Quality Management System
2.27	QMSR	Quality Management System Regulation (FDA)
2.28	Shafafiya	DoH platform for HCPCS coding and billing https://www.doh.gov.ae/en/Shafafiya
2.29	SLA	Service Level Agreement
2.30	Standard Provider Contract (SPC)	An agreement governing DME pricing and reimbursement.
2.31	Standard DME	DME not designed or customized for a specific individual's use.
2.32	TAT	Turnaround Time
2.33	TPA	Third-Party Administrator
2.34	UDI	Unique Device Identification

3. Policy Content

3.1 The Abu Dhabi Health System provides comprehensive healthcare services, including DME, to support patients' functional needs and prevent health deterioration.

3.2 This policy establishes rules for DME coverage, prescription, and management, ensuring compliance with FDA, EMA, MOHAP, and ISO 13485:2016 standards.

3.3 It addresses general DME (A1) and respiratory DME (A2), prioritizing patient safety, cost-effectiveness, and care quality.

3.4 Rules and Controls:

3.4.1 DME must be medically necessary, prescribed by a specialist, and approved by ADHTA FDA, EMA, or MOHAP.

3.4.2 Coverage includes purchase, rental, supplies, and replacements per SPC terms (A1, A2).

3.4.3 Exclusions include non-medical, duplicate, or non-approved devices (A1.2, A2.2).

3.4.4 Providers and Payers must use HCPCS codes via Shafafiya portal and maintain a dynamic DME list.

3.4.5 **Service Level Agreements (SLAs) and Turnaround Times (TATs) for DME maintenance shall include detailed protocols to ensure timely service and patient safety, incorporating the following requirements:**

3.4.5.1 Response to maintenance requests within 24 hours, ensuring initial assessment and communication with the patient and provider to initiate repairs or replacements.

3.4.5.2 Completion of corrective maintenance within 48 hours, or provision of a temporary replacement device if repairs cannot be completed within this timeframe. This includes:

3.4.5.2.1 For life-support DME (e.g., ventilators, oxygen concentrators), a temporary replacement must be provided if repair or replacement is expected to exceed 6 hours, in line with high-risk equipment management standards.

3.4.5.2.2 For assistive DME (e.g., wheelchairs, walkers), a temporary replacement must be provided if repair or replacement is expected to exceed 24 hours, supporting patient mobility and daily function.

3.4.5.2.3 For other DME (e.g., nebulizers for non-severe conditions), a temporary replacement must be provided if repair or replacement is expected to exceed 48 hours, maintaining treatment continuity.

3.4.5.3 Preventive maintenance schedules aligned with manufacturer recommendations, conducted at least annually, to proactively address wear and tear and prevent failures, as per ISO 13485:2016 quality management requirements for medical device maintenance.

3.4.5.4 Healthcare Provider Responsibilities: Healthcare providers are ultimately responsible for the end-to-end management of DME, including:

3.4.5.4.1 Facilitating patient inquiries by providing a dedicated contact point for reporting issues or requesting maintenance.

3.4.5.4.2 Coordinating with the company providing the DME to ensure timely repairs, replacements, and adherence to SLAs.

3.4.5.4.3 Overseeing the maintenance process, including scheduling preventive maintenance and documenting corrective actions, in compliance with MOHAP and international regulations.

3.4.5.4.4 Ensuring patient safety by verifying that replacements meet the same clinical specifications as the original device.

3.4.5.5 Escalation Process for Delays: If a DME supplier fails to provide a temporary replacement or complete maintenance within the specified timelines (6 hours for life-support DME, 24 hours for assistive DME, or 48 hours for other DME), the healthcare provider must escalate the issue to the supplier's senior management within 2 hours of the deadline, followed by a report to the payer via the Tamm platform within 4 hours, ensuring swift resolution.

3.4.5.6 Accountability Mechanism: Non-compliance by healthcare providers or DME suppliers with SLA timelines or responsibilities shall result in a formal review by the DoH, with potential penalties including suspension of provider accreditation or supplier contracts, as per MOHAP regulatory oversight, to be documented and addressed within 30 days.

3.4.5.7 Maintenance Quality Oversight: Healthcare providers must conduct quarterly audits of maintenance records and device performance, reporting any recurring issues to the DME supplier and MOHAP, with a corrective action plan required within 14 days if deficiencies are identified, ensuring ongoing reliability per ISO 13485:2016.

3.4.5.8 Patient Notification Protocol: In the event of a delay in maintenance or replacement, healthcare providers must notify affected patients within 2 hours of identifying the delay, providing details on the interim solution (e.g., loaner device) and expected resolution time, ensuring transparency and patient support.

3.4.5.9 Alignment with Best Practices: All SLA and TAT requirements (3.4.5.1 – 3.4.5.2) shall be benchmarked against international standards, including ANSI/AAMI EQ56:2013 for risk management and maintenance protocols, and ISO 13485:2016 for quality assurance, with annual reviews to incorporate emerging best practices.

3.5 Key Success Factors:

3.5.1 Patients must be educated on the correct use, safe handling, and regular maintenance of medical devices. Clear instructions shall ensure safe operation and upkeep to meet regulatory standards. Education shall be straightforward, accessible, and include checks for patient understanding.

3.5.2 Timely access to DME for eligible patients.

3.5.3 Compliance with international and MOHAP standards.
3.5.4 Reduced hospitalization through effective DME use.
3.5.5 Transparent reimbursement via Shafafiya platform.

3.6 Monitoring and Evaluation:

3.6.1 Vigilant monitoring and reporting for Durable Medical Equipment (DME) to be done by tracking any adverse events or issues that may arise during their use; and shall be reported to the DoH pharmacovigilance program as per the Standard on Medical Device Reporting (MDR).
3.6.2 A framework involving Providers, Payers, and DoH will monitor compliance via audits, patient complaints, and Shafafiya e-claims.
3.6.3 Evaluation domains include inputs, activities, outputs, and outcomes, with periodic updates.

3.7 Maintenance Requirements

3.7.1 All DME shall undergo regular preventive maintenance per manufacturer guidelines and ISO 13485:2016 to ensure functionality and patient safety.
3.7.2 Corrective maintenance shall be performed within 48 hours of a reported issue, with temporary replacement devices provided if delays exceed 72 hours.
3.7.3 Providers shall maintain records of maintenance activities, accessible via the Shafafiya platform, and report non-compliance to DoH.
3.7.4 A tag or sticker shall be affixed to each piece of equipment as documented evidence that the Planned Preventive Maintenance (PPM) schedule is being adhered to. The tag shall clearly indicate the date of the last completed maintenance, the next scheduled maintenance due date, and the name of the authorized maintenance provider.

4. Policy Roles and Responsibilities

4.1 Department of Health:

4.1.1 Drafts, implements, and oversees the DME policy, ensuring compliance with UAE Health Insurance Laws and MOHAP regulations.

4.1.2 Monitors DME safety, enforces standards, and arbitrates disputes.

4.2 Healthcare Providers:

4.2.1 Conduct evidence-based assessments, prescribe DME, and report incidents by DoH guidelines.

4.2.2 All DME dispensed by licensed Healthcare Providers, hospital pharmacies, or outpatient pharmacies affiliated with specific hospital groups shall be maintained by the dispensing entity. This includes responsibility for service maintenance, corrective maintenance, and preventive maintenance to ensure device functionality and patient safety, in compliance with ISO 13485:2016 and MOHAP post-market surveillance requirements. Patients shall be provided with clear instructions and accessible channels (e.g., contact numbers, email, or dedicated service portals) to reach designated personnel for maintenance requests or issues. The dispensing entity shall establish formal agreements with the DME agent, agency, or manufacturer's official representative to meet SLAs and TATs for maintenance and repairs, ensuring timely resolution of issues and compliance with DoH regulatory standards.

4.2.3 Healthcare Providers shall educate patients on proper DME use, routine maintenance, and troubleshooting, providing written or digital instructions in accessible formats (e.g., Arabic, English) at the time of dispensing. Education shall include guidance on recognizing device malfunctions and accessing maintenance services.

4.2.4 Healthcare Providers shall establish a process to monitor hazard notices through resources such as DoH, MOHAP, FDA, and other relevant authorities, and shall take appropriate action in the event of an equipment recall.

4.3 Third Party Administrators (TPA), Insurance providers:

4.3.1 Reimburse DME per SPC, maintain DME lists, and monitor compliance.

4.4 Vendors/Manufacturers:

4.4.1 Ensure DME meets FDA, EMA, MOHAP, ADHTA and ISO standards, provide warranties, and report adverse events.

4.4.2 Vendors and manufacturers shall provide technical support, spare parts, and training to dispensing entities to facilitate service, corrective, and preventive maintenance, ensuring compliance with SLAs and TATs as per agreements with Healthcare Providers.

4.4.3 All medical device incidents shall be reported in accordance with the DoH Standard on Medical Device Reporting (MDR).

5. Policy Scope of Implementation

5.1 This policy applies to:

5.1.1 All DoH licensed Healthcare Providers in the Emirate of Abu Dhabi.

5.1.2 All DoH authorized Health Payers.

5.1.3 All health insurance plans.

5.1.4 All DME used in outpatient settings, including home use, within the Emirate of Abu Dhabi.

5.1.5 Hospital pharmacies and outpatient pharmacies affiliated with DoH licensed Healthcare Providers, responsible for dispensing DME and coordinating maintenance per section 4.2.

6. Exempted from Policy Scope

6.1 If DME is used in inpatient hospital settings.

6.2 Disposable medical supplies (e.g., catheters, bandages).

6.3 Devices purchased outside Abu Dhabi without Payer pre-authorization.

6.4 Non-medical equipment (e.g., air conditioners or purifiers).

7. Monitoring and Evaluation

7.1 Key Success Factors:

7.1.1 Access: >95% of eligible patients receive prescribed DME within 10 calendar days.

7.1.2 Compliance: 100% of DME meets FDA, EMA, or MOHAP standards.

7.1.3 Safety: <1% adverse events reported annually via DoH surveillance.

7.1.4 Cost-Effectiveness: >80% of DME reimbursements use least costly, clinically appropriate options.

7.2 Monitoring:

7.2.1 Providers/Payers report incidents and access barriers to DoH.

7.2.2 The entity responsible for monitoring DME maintenance compliance, to be determined by the Department of Health (DoH), shall utilize provider-submitted maintenance logs, patient feedback, and Shafafiya platform data, with annual audits to verify adherence to SLAs and TATs.

7.3 Evaluation:

7.3.1 Annual review of inputs, activities, outputs, and outcomes.

7.3.2 Policy updates based on stakeholder feedback and clinical evidence.

8. Enforcement and Sanction

8.1 DoH may impose sanctions in relation to any breach of requirements under this Standard in accordance with the disciplinary regulation of the healthcare sector.

9. Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1	2021	MOHAP Medical Devices Regulation	https://mohap.gov.ae/en/w/registration-of-a-medical-equipment
2	2021	DoH Medical Devices Post Marketing Surveillance System	https://www.doh.gov.ae/en/research/Dashboard/Post-Marketing-Surveillance-Program
3	2021	NICE TA139: OSA guidelines for CPAP	https://www.nice.org.uk/guidance/ta139
4	2023	ATS/ERS COPD Guidelines Clinical Practice Guidelines, Statements & Reports	https://site.thoracic.org/clinicians-researchers/clinical-practice-guidelines-statements-reports
5	2023	Standard On Medical Device Reporting (MDR)	https://www.doh.gov.ae/-/media/9407BE65FA9146CDBE6BA4ABB2DECA2F.ashx
6	2025	Standard for Patient Support / Affordability Programs in the Emirate of Abu Dhabi	https://www.doh.gov.ae/-/media/C715F96BEAC84B1C80FEEB5A065FE243.ashx
7	2023	Standard for the Principles and Procedures Governing the Recovery of Payment for Healthcare Services under the Health Insurance Scheme	https://www.doh.gov.ae/-/media/A863F6DE8D2C4CBC8279F7666CACC715.ashx
8	2016	ISO 13485:2016 Quality management for DME	https://www.iso.org/standard/59752.html
9	2019	ISO 14971:2019 Risk management for DME	https://www.iso.org/standard/72704.html
10	2024	American Academy of Sleep Medicine	https://aasm.org/
11	2021	Centers for Medicare and Medicaid Services	https://www.cms.gov/about-cms
12	2023	American Association for Respiratory Care	https://www.aarc.org/
13	2025	Update of Standard Provider Contract	https://www.doh.gov.ae/en/resources/Circulars

A1 Appendix (1): Requirements for Access to DME

A1.1 Coverage Requirements

A1.1.1 Purchase of DME is covered if:

A1.1.1.1 In accordance with the insurance product.

A1.1.1.2 Determined to be medically necessary.

A1.1.1.3 It meets all the DME inclusion criteria specified in this Appendix.

A1.1.2 Coverage for DMEs shall include:

A1.1.2.1 Purchase of prescribed equipment.

A1.1.2.2 Purchase of "standard" DME unless the need of "above the standard specifications" is supported by evidence justifying its medical necessity.

A1.1.2.3 Supplies necessary for effective functioning of the DME.

A1.1.2.4 Replacement of DMEs shall be authorized as per the life span of the equipment and manufacturers' recommendations, normal wear and tear as per manufacturers' guidelines, or in case of damage due to no fault of the patient.

A1.1.3 Coverage is limited to the agreed price and markup as per the Standard Provider Contract.

A1.1.4 Coverage is limited to the least costly and clinically appropriate DME without compromising patient safety and medical needs.

A1.1.5 Patients may top up their coverage to purchase a more costly DME of preference.

A1.1.6 DME benefit shall only be available through the Payer's network of DoH-licensed Healthcare Providers.

A1.1.7 Damage of purchased equipment due to manufacturing defects shall be covered under the manufacturer/vendor's standard warranty.

A1.2 Exclusions to Coverage Requirements

A1.2.1 Repair or replacement of purchased equipment damaged due to neglect, theft, or abuse.

A1.2.2 Duplicate equipment that is intended to be used as a back-up device, for multiple residences, or for travelling.

A1.2.3 Equipment that is primarily and customarily used for non-medical purposes, although it may have some remote medically related use for convenience, e.g., air conditioner uses by a cardiac patient to lower room temperature.

A1.2.4 DME that meets the same medical need as the old item that the member is using but in a more efficient manner, convenient, or cosmetically appealing when there is no change in the member's condition.

A1.2.5 DME that have been purchased by the patient outside the Emirate of Abu Dhabi.

A1.3 Healthcare Providers and Insurers' Requirements

A1.3.1 The treating physician must always conduct evidence-based DME assessment prior to the issuance of a DME prescription.

A1.3.2 The prescribing specialist/consultant must compile the necessary documentation to support the purchase or replacement of the DME; and when required, submit the required documentation (including risk assessment) to the payer for authorization.

A1.3.3 Pre-approval is required for all DME items, regardless of cost, to be submitted to the payer prior to coverage.

A1.3.4 Agree on a DME list and reference prices for reimbursable DME and update this list accordingly.

A1.3.5 Healthcare Providers and Payers must make use of applicable HCPCS codes and modifiers for billing available on the Shafafiya platform: https://www.doh.gov.ae/en/Shafafiya

A1.3.6 Payers shall cover replacement due to normal life of DME as per manufacturers' guidelines

A2 Appendix (2): Requirements for Access to Respiratory-Related Durable Medical Equipment (DME)

A2.1 This appendix outlines specific requirements for the coverage, prescription, and management of respiratory-related Durable Medical Equipment (DME) within the Abu Dhabi Health System, as established by the DoH in the Policy on Durable Medical Equipment.

A2.2 Complements the general DME requirements in A1 and ensures compliance with FDA, EMA, and UAE Ministry of Health and Prevention (MOHAP) standards for devices used in outpatient settings under the Thiqa insurance program and other schemes.

A2.1 Coverage Requirements

A2.1.1 Eligibility for Coverage: Purchase or rental of respiratory-related DME is covered if:

A2.1.1.1 Prescribed by a licensed pulmonologist, sleep medicine specialist, or other relevant specialist in accordance with the patient's insurance product and schedule of benefits, as defined in section 2.12 (SPC) and A1.1.1.

A2.1.1.2 Determined to be medically necessary based on evidence-based clinical guidelines from the American Thoracic Society (ATS, 2023), European Respiratory Society (ERS), World Health Organization (WHO), or National Institute for Health and Care Excellence (NICE, TA139, 2021) for conditions including but not limited to:

A2.1.1.2.1 Obstructive Sleep Apnea (OSA)

A2.1.1.2.2 Chronic Obstructive Pulmonary Disease (COPD)

A2.1.1.2.3 Chronic respiratory failure

A2.1.1.2.4 Neuromuscular disorders

A2.1.1.2.5 Cystic fibrosis

A2.1.1.2.6 Bronchiectasis

A2.1.1.2.7 Obesity hypoventilation syndrome

A2.1.1.2.8 Congenital central hypoventilation syndrome

A2.1.1.2.9 Chronic lung disease of infancy (e.g., bronchopulmonary dysplasia)

A2.1.1.2.10 Hypoventilation syndromes

A2.1.1.2.11 Interstitial lung disease

A2.1.1.2.12 Pulmonary fibrosis

A2.1.1.3 The device meets all DME inclusion criteria specified in 2.5 and is approved by an internationally recognized regulatory authority, including:

A2.1.1.3.1 U.S. Food and Drug Administration (FDA) via Premarket Notification (510(k)) or Premarket Approval (PMA) for Class II or III devices.

A2.1.1.3.2 European Medicines Agency (EMA) or EU Notified Bodies with CE marking under Regulation (EU) 2017/745.

A2.1.1.3.3 UAE Ministry of Health and Prevention (MOHAP) or other credible authorities (e.g., Health Canada, TGA).

A2.1.1.4 The device complies with ISO 13485:2016 for quality management systems and device-specific standards:

A2.1.1.4.1 ISO 80601-2-70:2020 (CPAP/BiPAP)

A2.1.1.4.2 ISO 80601-2-12:2020 (ventilators)

A2.1.1.4.3 ISO 80601-2-72:2020 (HFCWO)

A2.1.1.4.4 ISO 27427:2013 (nebulizers).

A2.1.2 Covered Items and Services

A2.1.2.0.1 This section specifies covered respiratory-related DME, including purchase, rental, supplies, and maintenance, as per the DoH Durable Medical Equipment Policy.

A2.1.2.0.2 Coverage complies with FDA, EMA, MOHAP standards, ISO 13485:2016, and evidence-based guidelines (ATS/ERS 2023, NICE TA139 2021, WHO).
A2.1.2.1 Purchase or Rental of Prescribed Respiratory DME.
A2.1.2.1.1 The following table (see separate artifact) summarizes covered respiratory DME when prescribed by a licensed pulmonologist, sleep medicine specialist, or relevant specialist, per insurance product and schedule of benefits.

E**quipment Category**	**Clinical Indications**	**HCPCS Codes**
Continuous Positive Airway Pressure (CPAP) and AutoCPAP Machines	Obstructive Sleep Apnea (OSA) with Apnea-Hypopnea Index (AHI) ≥15 events/hour, or AHI 5–14 events/hour with excessive daytime sleepiness (Epworth Sleepiness Scale, NICE TA139). AutoCPAP for mild OSA if high pressure needed intermittently or fixed-level CPAP intolerable.	E0601: CPAP device (includes integrated humidifier, not separately billed). A7034: Nasal/full face mask. A7035: Headgear. A7037: Tubing.
Bilevel Positive Airway Pressure (BiPAP) Machines	Patients intolerant to high CPAP pressures or with barotrauma complications (e.g., ear infections, bloating). OSA, chronic respiratory failure, or neuromuscular disorders where CPAP is insufficient (ATS/ERS 2023).	E0470: BiPAP, without backup rate. E0471: BiPAP, with backup rate. A7034: Nasal/full face mask. A7035: Headgear. A7037: Tubing.
Nebulizers	Large drug doses, acute severe asthma, COPD exacerbations, chronic lung disease where handheld inhalers are ineffective, or antibiotics unavailable as inhalers (ATS/ERS 2023).	E0570: Nebulizer with compressor. A7005: Non-disposable administration set. A7013: Disposable filter.
Home Ventilators (Non-Invasive Interface)	Neuromuscular disease, thoracic restrictive disease, chronic respiratory failure from COPD, congenital central hypoventilation syndrome, chronic lung disease of infancy, obesity hypoventilation syndrome, or restrictive chest wall disorders where BiPAP fails to improve hypercapnia/oxygenation; no continuous (24-hour) ventilation required. Continued use requires documented compliance and persistent clinical need (ATS/ERS 2023).	E0466/E0465: Home ventilator, non-invasive interface. A7034: Mask interface. A7035: Headgear. A7037: Tubing.
High-Frequency Chest Wall Oscillation (HFCWO) Devices	Bronchiectasis (CT-confirmed, daily productive cough ≥6 months or frequent exacerbations), cystic fibrosis, immotile cilia syndrome, specific neuromuscular diseases (e.g., acid maltase deficiency, amyotrophic lateral sclerosis, muscular dystrophy), or lung transplant recipients within 6 months post-operatively unable to tolerate standard chest physiotherapy (ATS/ERS 2023).	E0483: HFCWO system. A7025: Disposable vest. A7026: Reusable vest.
Portable Oxygen Concentrators	Hypoxemia with arterial PaO2 ≤55 mm Hg or oxygen saturation ≤88% at rest, during sleep, or exercise; or	E1390: Oxygen concentrator, single

	PaO2 56–59 mm Hg with congestive heart failure, pulmonary hypertension, or erythrocythemia (hematocrit >56%) (WHO).	port. E1392: Portable oxygen concentrator, rental. A4615: Nasal cannula.

A2.1.2.1.2 Regulatory Standards: All devices must meet ISO 80601-2-70:2020 (CPAP/BiPAP), ISO 80601-2-12:2020 (ventilators), ISO 80601-2-72:2020 (HFCWO), ISO 27427:2013 (nebulizers), and FDA 510(k)/PMA or EMA CE marking requirements.
A2.1.2.1.1.1 Continuous Positive Airway Pressure (CPAP) and AutoCPAP Machines
A2.1.2.1.1.2 Indicated for OSA with Apnea-Hypopnea Index (AHI) ≥15 events/hour, or AHI 5–14 events/hour with excessive daytime sleepiness (assessed via Epworth Sleepiness Scale, NICE TA139).
A2.1.2.1.1.3 AutoCPAP considered for mild OSA if high pressure is needed intermittently or fixed-level CPAP is intolerable.
A2.1.2.1.2.1 Bilevel Positive Airway Pressure (BiPAP) Machines
A2.1.2.1.2.2 Indicated for patients intolerant to high CPAP pressures or with barotrauma complications (e.g., ear infections, bloating).
A2.1.2.1.2.3 Also for OSA, chronic respiratory failure, or neuromuscular disorders where CPAP is insufficient (ATS/ERS 2023).
A2.1.2.1.3.1 Nebulizers
A2.1.2.1.3.2 Indicated for large drug doses, acute severe asthma, COPD exacerbations, chronic lung disease where handheld inhalers are ineffective, or when antibiotics are unavailable as inhalers (ATS/ERS 2023).
A2.1.2.1.4.1 Home Ventilators with Non-Invasive Interface
A2.1.2.1.4.2 Indicated for neuromuscular disease, thoracic restrictive disease, chronic respiratory failure from COPD, congenital central hypoventilation syndrome, chronic lung disease of infancy, obesity hypoventilation syndrome, or restrictive chest wall disorders, where BiPAP fails to improve hypercapnia/oxygenation and continuous (24-hour) ventilation is not required.
A2.1.2.1.4.3 Continued use requires documentation of compliant usage and persistent clinical need.
A2.1.2.1.5.1 High-Frequency Chest Wall Oscillation (HFCWO) Devices
A2.1.2.1.5.2 Indicated for bronchiectasis (confirmed by CT scan with daily productive cough ≥6 months or frequent exacerbations), cystic fibrosis, immotile cilia syndrome, specific neuromuscular diseases (e.g., acid maltase deficiency, amyotrophic lateral sclerosis, muscular dystrophy), or lung transplant recipients within 6 months post-operatively unable to tolerate standard chest physiotherapy.
A2.1.2.1.6.1 Portable Oxygen Concentrators
A2.1.2.1.6.2 Indicated for hypoxemia with arterial PaO2 ≤55 mm Hg or oxygen saturation ≤88% at rest, during sleep, or exercise; or PaO2 56–59 mm Hg with conditions like congestive heart failure, pulmonary hypertension, or erythrocythemia (hematocrit >56%), per WHO guidelines.
A2.1.2.2 Purchase of Standard DME
A2.1.2.2.1 Purchase of "standard" respiratory DME, unless non-standard/customized specifications (e.g., pediatric settings, high-flow oxygen systems) are justified by clinical evidence per A2.1.1.2 (evidence-based guidelines).
A2.1.2.3 Supplies
A2.1.2.3.1 Supplies necessary for effective functioning, such as CPAP/BiPAP masks, tubing, filters, nebulizer kits, and oxygen delivery accessories, per manufacturer guidelines.

A2.1.2.4 Consumable Disposables
A2.1.2.4.1 Consumable disposables such as CPAP/BiPAP masks, tubing, filters, nebulizer kits, and oxygen delivery accessories, shall be dispensed in alignment with the warranty cycle of the associated respiratory DME device to ensure continuous functionality and patient safety.
A2.1.2.4.2 Replacement of these consumables shall be covered within the warranty period if defective, as per manufacturer guidelines and MOHAP regulations.
A2.1.2.5 Replacement
A2.1.2.5.1 Replacement of respiratory DME as per the equipment's lifespan, normal wear and tear, or manufacturer recommendations, provided clinical need persists, as per A1.1.2.4.
A2.1.2.6 Maintenance
A2.1.2.6.1 Maintenance and servicing to ensure safety and performance, per ISO 13485:2016 and MOHAP post-market surveillance requirements.
A2.1.2.7 Billing and Compliance
A2.1.2.7.1 Providers and Payers must use HCPCS codes via the Tamm platform (https://www.tamm.abudhabi/) for billing, maintaining a dynamic list of reimbursable DME (A1.3.5, A2.3.2.2).
A2.1.2.7.2 HCPCS codes are based on CMS standards; verify specific codes via Tamm platform for Abu Dhabi compliance.
A2.1.2.7.3 Humidifiers for CPAP devices are integral to E0601 and not separately billed.

A2.1.3 Cost and Reimbursement:
A2.1.3.1 Coverage is limited to the agreed price and markup per the Standard Provider Contract (SPC), as per A1.1.3.
A2.1.3.2 Coverage prioritizes the most cost-effective, clinically appropriate respiratory DME, ensuring cost-efficiency without compromising safety or medical needs.
A2.1.3.3 Patients may top up coverage for preferred, non-standard respiratory DME, provided base medical needs are met, as per A1.1.5.
A2.1.3.4 Coverage is only available through DoH-licensed Healthcare Providers within the Payer's network, as per A1.1.6.

A2.1.4 Warranty and Defects:
A2.1.4.1 Devices must carry standardized warranty periods reflecting expected lifespan, as per A1.1.7
A2.1.4.1.1 CPAP Devices: 3 years
A2.1.4.1.2 BiPAP Devices: 3 years
A2.1.4.1.3 HFCWO Devices: 3 years
A2.1.4.1.4 Home Ventilators: 5 years
A2.1.4.1.5 Nebulizers: 3 years
A2.1.4.1.6 Facial masks, including full face masks and nasal masks, must carry a standardized warranty period of 9 months, covering defects in materials or workmanship, per FDA and EMA post-market surveillance requirements.

A2.1.4.2 Damage due to manufacturing defects is covered under the manufacturer's warranty, per FDA and EMA post-market surveillance requirements.
A2.1.4.3 Warranty excludes consumables and batteries, if applicable.

A2.2 Exclusions to Coverage Requirements

A2.2.1 Respiratory-related DME will not be covered if they meet any exclusion criteria in A1.2, including:

A2.2.1.1 Damaged due to patient neglect, theft, or abuse.

A2.2.1.2 Intended as a duplicate for backup, multiple residences, or travel.

A2.2.1.3 Primarily used for non-medical purposes (e.g., air purifiers for comfort) or offering only convenience/cosmetic benefits.

A2.2.1.4 Enhances efficiency or convenience without a change in clinical condition (e.g., upgrading CPAP without medical justification).

A2.2.1.5 DME that have been purchased by the patient outside the Emirate of Abu Dhabi.

A2.2.1.6 Lacks approval from recognized authorities (e.g., FDA 510(k), EMA CE marking) or fails to meet ISO standards (e.g., ISO 80601-2-70:2020, ISO 80601-2-12:2020).

A2.3 Healthcare Providers and Insurers' Requirements

A2.3.1 Clinical Assessment and Prescription:

A2.3.1.1 The treating physician must conduct an evidence-based assessment, including diagnostic tests (e.g., polysomnography for OSA, arterial blood gas for oxygen therapy, CT scan for bronchiectasis), to justify medical necessity per ATS/ERS/WHO/NICE guidelines, as per A1.3.1.

A2.3.1.2 The prescribing specialist must document clinical indications, expected duration of use, and compliance with guidelines, submitting to the Payer for authorization, as per A1.3.2.

A2.3.2 Authorization and Documentation:

A2.3.2.1 Pre-approval is required for all respiratory DME items, regardless of cost, supported by clinical documentation and risk assessment per ISO 14971:2019, as per A1.3.3.

A2.3.2.2 Providers must use HCPCS codes and modifiers for billing, per the Shafafiya platform, as per A1.3.5.

A2.3.3 Quality and Compliance:

A2.3.3.1 Providers and Payers must maintain a dynamic list of reimbursable respiratory DME, updated with reference prices and regulatory approvals (e.g., FDA 510(k), CE marking), as per A1.3.4.

A2.3.3.2 Devices must comply with:

A2.3.3.2.1 ISO 80601-2-70:2020 / ISO 80601-2-70:2015 (CPAP/BiPAP)

A2.3.3.2.2 ISO 80601-2-72:2020 / ISO 80601-2-72:2015 (HFCWO)

A2.3.3.2.3 ISO 80601-2-72:2020 / ISO 80601-2-72:2015 (ventilators)

A2.3.3.2.4 ISO 27427:2013 (nebulizers)

A2.3.3.2.5 ISO 14971:2019 for risk management

A2.3.3.2.6 ISO 20416:2020 for post-market surveillance

A2.3.3.3 Vendors must implement a Corrective and Preventive Actions (CAPA) system and report adverse events per MOHAP regulations and DoH Medical Devices Post Marketing Surveillance System (2021).

A2.3.3.4 Payers must cover replacements based on device lifespan and clinical need, as per A1.3.6.

A2.3.4 Monitoring and Reporting:

A2.3.4.1 Providers must report medical incidents or deficiencies related to respiratory DME to DoH Standard on Medical Device Reporting (MDR), as per 4.3.

A2.3.4.2 Payers and Providers must monitor patient compliance (e.g., CPAP adherence data) and report access barriers to DoH, as per 4.4.3

A2.4 List of Covered Respiratory DME (Dynamic)

A2.4.1 The following non-exhaustive list of respiratory DME is covered, subject to updates based on clinical evidence, regulatory approvals, and DoH guidelines, as per 3.4.4:

A2.4.1.1 CPAP/AutoCPAP Machines (ISO 80601-2-70:2020, FDA 510(k))

A2.4.1.2 BiPAP Machines (ISO 80601-2-70:2020, FDA 510(k))

A2.4.1.3 Nebulizers (ISO 27427:2013, FDA 510(k))

A2.4.1.4 Home Ventilators (ISO 80601-2-12:2020, FDA 510(k)/PMA)

A2.4.1.5 HFCWO Devices (ISO 80601-2-72:2020, FDA 510(k))

A2.4.1.6 Portable Oxygen Concentrators (FDA 510(k))

A2.4.1.7 Accessories: Masks, tubing, filters, nebulizer kits, oxygen delivery systems.

A2.4.2 This list will be maintained by DoH in collaboration with Providers and Payers, incorporating new devices approved by FDA, EMA, or MOHAP.

Appendix (A3): Orthotics and Prosthetics (O&P)

(Part of the Durable Medical Equipment (DME) Policy)

Table of Contents

A3.1 Purpose and Scope

A3.1.1 This Appendix establishes the mandatory regulatory, clinical, technical, quality, procurement and reimbursement requirements governing Orthotics and Prosthetics (O&P) services and devices within the DoH Durable Medical Equipment (DME) regulatory framework.

A3.1.2 This Appendix applies to the full O&P lifecycle including: clinical evaluation, prescription, eligibility, assessment, ordering, procurement governance, fabrication, assembly, fitting, delivery, training, follow-up, repairs, replacement, maintenance, safety monitoring, documentation, reporting, reimbursement and TPA verification.

A3.1.3 This Appendix is binding for all DoH-licensed healthcare providers, prescribers, O&P workshops, suppliers, importers, manufacturers, distributors, agents and TPAs engaged in O&P service provision within the Emirate of Abu Dhabi.

A3.1.4 This Appendix forms an integral part of the DoH DME Policy and shall be applied in conjunction with applicable national and international regulatory requirements.

A3.2 Objectives

A3.2.1 Ensure that all eligible patients receive clinically justified and timely access to safe, effective and high-quality O&P devices.

A3.2.2 Ensure strict adherence to validated international and national regulatory and quality standards for all O&P devices and components.

A3.2.3 Prevent downgrading, substitution, under-specification or use of non-compliant O&P components or devices.

A3.2.4 Promote transparent, traceable and accountable procurement and reimbursement processes that protect the healthcare system from improper practices.

A3.2.5 Support measurable improvements in functional health, mobility, participation and independence in line with established rehabilitation frameworks.

A3.2.6 Strengthen multidisciplinary coordination and ensure continuity of care through the full O&P service pathway.

A3.2.7 Maintain end-to-end traceability to ensure accountability, safety and quality oversight from prescription through disposal.

A3.2.8 Facilitate system-wide monitoring, auditing and continuous improvement of O&P services.

A3.3 Clinical Prescription and Eligibility

A3.3.1 Authorized Prescribers and Scope

A3.3.1.1 Prescriptions for O&P devices shall be issued only by authorised clinicians acting strictly within recognised scope. Authorised clinicians include: physical medicine and rehabilitation physicians; orthopaedic surgeons; neurologists (neurological indications only); neurosurgeons (neurological and spinal indications); podiatrists (foot/ankle orthoses); vascular surgeons (vascular limb indications); plastic surgeons (reconstructive limb conditions); paediatricians (screening and paediatric care with specialist confirmation where required); diabetologists (diabetic foot O&P devices); and certified prosthetist/orthotists acting under

the prescribing pathway specified in A3.3.1.10. The full justification and clinical reasoning supporting the prescription must be documented and retained.

A3.3.1.2 Certified prosthetists/orthotists may prescribe only when operating under a documented collaborative practice agreement or when clinically managing a continuation device for which a physician evaluation within the preceding six (6) months is available.

A3.3.1.3 Physiotherapists and occupational therapists may provide functional assessments but shall not independently prescribe O&P devices.

A3.3.1.4 Providers must retain records verifying the prescriber's licensing, credentials and scope.

A3.3.1.5 Prescriptions shall specify device category, design features, functional level, required components, special instructions and expected lifespan.

A3.3.1.6 Prescriptions shall indicate whether the device represents an initial provision, replacement, upgrade, modification, adjustment or repair.

A3.3.1.7 Paediatric prescriptions must include growth-related considerations and review intervals.

A3.3.1.8 Clinically relevant comorbidities influencing device selection shall be documented.

A3.3.1.9 No prescriber's instructions may be altered by suppliers; any modification must be prescriber-approved and fully documented.

A3.3.1.10 Prosthetist/orthotist prescribing may occur only for continuation devices where the clinical condition is stable and within the pathway defined in A3.3.1.2.

A3.3.2 Functional Classification and Assessment Requirements

A3.3.2.1 Prosthetic prescriptions shall include the patient's functional mobility classification (K-Level or equivalent), with documented rationale.

A3.3.2.2 Orthotic prescriptions shall reference validated functional, or gait assessments appropriate to the device category.

A3.3.2.3 Assessments shall include date, test type, scoring, interpretation and explicit linkage to device selection.

A3.3.2.4 Re-assessment is required prior to replacements or major adjustments unless clinically inappropriate and justified.

A3.3.3 Clinical Documentation Requirements

A3.3.3.1 ICD diagnosis and relevant clinical history.

A3.3.3.2 Functional assessment results supporting device selection.

A3.3.3.3 Rehabilitation objectives, expected outcomes and replacement triggers.

A3.3.3.4 Multidisciplinary inputs where applicable.

A3.3.3.5 Outcome measurement tools where clinically appropriate.

A3.3.3.6 Risk factors influencing material or component selection.

A3.3.4 Multidisciplinary Review for Complex Devices

A3.3.4.1 Complex and high-risk devices shall undergo structured multidisciplinary review including the prescribing clinician and a certified prosthetist/orthotist.

A3.3.4.2 Review notes, rationale and expected outcomes must be retained.

A3.3.5 Prescription Validity

A3.3.5.1 Standard adult prescriptions remain valid for six (6) months.

A3.3.5.2 Paediatric prescriptions remain valid for three (3) months.

A3.3.5.3 Expired prescriptions cannot be used for ordering or claim submission.

A3.3.6 Rehabilitation Alignment

A3.3.6.1 Device selection must correlate with documented rehabilitation goals.

A3.3.6.2 Goals shall be reviewed during follow-up.

A3.4 Quality and Technical Standards

A3.4.1 Standards and Regulatory Authorisation

A3.4.1.1 All O&P devices shall comply with ISO 13485:2016 + Amd 1:2024; ISO 14971:2019 + Amd 1:2023; ISO 22523:2021; ISO 10328:2016; ISO 10993 series; ISO 15223-1:2024; FDA 21 CFR Part 820 (QMSR, 2024); EU MDR 2017/745 (as amended).

A3.4.1.2 Suppliers must maintain valid documentation demonstrating conformity.

A3.4.1.3 Non-compliant devices are prohibited from procurement and patient use.

A3.4.2 Local Fabrication Requirements

A3.4.2.1 Local workshops shall operate under a QMS aligned to ISO 13485.

A3.4.2.2 Providers shall maintain fabrication logs documenting materials, components, casting, alignment, lamination, finishing and inspections.

A3.4.2.3 Providers shall maintain documented traceability linking prescription, fabrication process and final device.

A3.4.3 Materials and Biocompatibility

A3.4.3.1 All materials must meet structural performance and safety requirements applicable to their intended use.

A3.4.3.2 Providers rely on supplier-issued declarations of conformity; standalone biocompatibility testing by providers is not required.

A3.4.4 Labelling, Serialisation and IFU

A3.4.4.1 Components must include UDI or serial identifiers where applicable.

A3.4.4.2 Custom-fabricated devices must be traceable through workshop records and patient files.

A3.4.4.3 IFU shall be available in Arabic and English where applicable.

A3.5 Workshop Licensing and Quality System Requirements

A3.5.1.1 All O&P service delivery, fabrication or assembly must occur in a DoH-licensed facility.

A3.5.1.2 Facilities must maintain a QMS aligned with ISO 13485:2016 + Amd 1:2024.

A3.5.2.1 Records of equipment calibration, verification and environmental conditions shall be retained.

A3.5.2.2 Technical staff competence must be documented.

A3.5.2.3 Infection control, safety protocols and material handling procedures must be established.

A3.5.3.1 Workshops must maintain appropriate ventilation, dust extraction and environmental controls.

A3.5.4.1 Facilities shall be subject to periodic DoH audits.

A3.5.4.2 Transitional compliance timelines may be approved solely by DoH.

A3.6 Fabrication, Fitting, and Delivery Procedures

A3.6.1.1 Every device must be assigned a unique identifier recorded in clinical and supplier records.

A3.6.2.1 Fitting, alignment and adjustments must be completed by a certified prosthetist/orthotist.

A3.6.2.2 Supervision and competency documentation shall be maintained.

A3.6.3.1 Verification tests must be performed and recorded, including gait or pressure mapping where indicated.

A3.6.4.1 Delivery shall be documented using a Delivery and Fitting Acceptance Note as defined in Annex A3.2.

A3.6.4.2 The acceptance note must include device identifiers, fitting confirmation, education checklist and signatures of the patient and provider.

A3.6.4.3 Providers shall upload the acceptance note and invoice to the patient record and DoH interface within five (5) working days.

A3.6.4.4 Physiotherapist involvement is required for functionally guided devices.

A3.7 Post-Delivery Follow-Up and Maintenance

A3.7.1.1 Initial follow-up shall occur within two (2) to four (4) weeks after delivery.

A3.7.2.1 Paediatric patients require review every three (3) to six (6) months.

A3.7.2.2 High-activity prosthetic users require review every six (6) months.

A3.7.2.3 Other patient groups require annual review unless otherwise indicated.

A3.7.3.1 Routine maintenance must follow manufacturer instructions.

A3.7.3.2 Where guidance is absent, providers shall document risk-based schedules.

A3.7.4.1 Loaner devices shall be provided when repair times exceed seven (7) working days.

A3.7.5.1 Providers must notify patients of delays within two (2) hours for urgent cases and within twenty-four (24) hours for non-urgent delays.

A3.8 Supplier Obligations and Technical File Requirements

A3.8.1 Technical File Availability

A3.8.1.1 Suppliers shall maintain a complete Technical File and provide it within ten (10) working days upon DoH request.

A3.8.2 Minimum Technical File Contents

A3.8.2.1 Regulatory authorisation documentation.
A3.8.2.2 Quality certificates.
A3.8.2.3 Product specifications.
A3.8.2.4 Component lists.
A3.8.2.5 Material declarations.
A3.8.2.6 Structural test reports.
A3.8.2.7 IFU documents.
A3.8.2.8 Warranty terms.
A3.8.2.9 Service life information.
A3.8.2.10 Risk management summary.
A3.8.2.11 Adverse event register.
A3.8.2.12 PMS records.

A3.8.2.13 Device history records.
A3.8.2.14 Batch/serial information.
A3.8.2.15 Component traceability.
A3.8.2.16 Storage/transport conditions.
A3.8.2.17 Specification change history.
A3.8.2.18 Supplier authenticity documentation.
A3.8.2.19 Prescriber-approved modifications.
A3.8.2.20 Recall history.
A3.8.2.21 CAPA records.

A3.9 Governance, and TPA Submission Rules

A3.9.1 Reimbursement Documentation Requirements
A3.9.1.1 All reimbursement claims for O&P devices shall be supported by a **commercial tax invoice** (not a quotation) issued by the authorised supplier and bearing supplier legal name, supplier licence number, device name, model, HCPCS or equivalent coding, serial/UDI, quantity, unit price, total price, date of issue and delivery reference.
A3.9.1.2 Every claim must attach the signed Delivery and Fitting Acceptance Note as per Annex A3.2.
A3.9.1.3 Claims that do not include the required invoice, acceptance note, prescriber documentation and clinical justification shall be rejected and may be subject to recovery action.

A3.9.2 TPA Responsibilities and Validation Requirements
A3.9.2.1 TPAs shall validate invoice authenticity, confirm delivered product matches authorization details and ensure the Delivery and Fitting Acceptance Note is present and correctly completed.
A3.9.2.2 TPAs shall perform automated and manual adjudication checks against the DoH O&P Registry and against the original clinical authorization.
A3.9.2.3 TPAs shall retain adjudication logs, rule-sets and decision rationale for at least seven (7) years and provide these on request to DoH.

A3.9.3 High-Value Claim Controls and Shadow Adjudication
A3.9.3.1 Claims above a financial threshold determined by DoH shall be flagged for DoH shadow adjudication and pre-payment review.
A3.9.3.2 High-value claims shall require additional supporting documentation such as Technical File excerpts, manufacturer declarations or clinical multidisciplinary review notes.

A3.9.4 Invoice Data Requirements and Retention
A3.9.4.1 Providers and TPAs shall retain procurement, delivery and claim records for at least seven (7) years and make documentation available to DoH within five (5) working days of request.
A3.9.4.2 Electronic submission standards shall include metadata enabling matching of invoice line items to device UDI/serials and patient acceptance notes.

A3.9.5 Price Transparency and Audit Rights
A3.9.5.1 DoH may require confidential supplier cost breakdowns (cost build-up) to validate price reasonableness for procurement or to investigate suspected irregularities. Such information shall be submitted under DoH confidentiality protections.
A3.9.5.2 Failure to provide requested confidential cost information may trigger contract review, financial recovery, or other enforcement actions.

A3.9.6 Random Audits and Recovery Triggers
A3.9.6.1 DoH shall have the authority to conduct random audits of procurement and claims in coordination with TPAs and providers.
A3.9.6.2 Discrepancies between invoiced, procured and delivered devices shall trigger financial investigation and may result in recovery of funds and supplier or provider sanctions.

A3.10 Audit and Compliance

A3.10.1 DoH Audit Program
A3.10.1.1 DoH shall conduct periodic announced and unannounced audits of suppliers, workshops, providers and TPAs to verify compliance with this Appendix and with national device regulations.

A3.10.2 Audit Classification and CAPA Timelines
A3.10.2.1 Audit findings shall be classified as Critical, Major or Minor.
A3.10.2.2 CAPA timelines are defined as follows: Critical — CAPA plan submitted within ten (10) working days and implemented within thirty (30) calendar days; Major — CAPA plan submitted within twenty (20) working days and implemented within sixty (60) calendar days; Minor — CAPA plan submitted within thirty (30) working days and implemented within ninety (90) calendar days.
A3.10.2.3 DoH shall verify CAPA effectiveness within a DoH-specified verification period and may require third-party validation when necessary.

A3.10.3 Appeal and Due Process
A3.10.3.1 Auditees shall have the right to submit a written appeal within fifteen (15) working days of receipt of the audit report. Appeals shall be considered under DoH procedural rules.

A3.10.4 Enforcement Triggers
A3.10.4.1 Repeated non-conformities, critical safety findings, evidence of deliberate misrepresentation or fraudulent activity shall be escalated to enforcement action per Clause A3.15.

A3.11 Data Reporting and Transparency

A3.11.1 Adverse Event Reporting Timelines
A3.11.1.1 Suppliers and providers shall report serious device-related incidents to DoH within forty-eight (48) hours of awareness and submit an initial investigation summary within fifteen (15) working days. Serious device-related incidents are those that cause death, are life-threatening, result in permanent impairment or substantial functional loss, require or prolong hospitalization, or could lead to such outcomes.

A3.11.2 O&P Registry Reporting Requirements
A3.11.2.1 Providers shall submit quarterly data to the DoH O&P Registry including device category, serial/UDI, patient functional outcomes, follow-up status, repair records, rework/return events, and adverse incidents.

A3.11.3 Field Safety Notices and Recalls
A3.11.3.1 Suppliers shall notify DoH of field safety notices or recalls within forty-eight (48) hours of issuance and coordinate communication with providers and affected patients.

A3.11.4 Data Security and Privacy
A3.11.4.1 All data submissions must comply with applicable UAE data protection and cybersecurity regulations. Data transfers shall be encrypted and access-controlled.

A3.11.5 Public Transparency and Performance Publication
A3.11.5.1 DoH may publish anonymised performance dashboards reflecting supplier performance, incident rates, and KPI compliance to promote transparency and quality improvement.

A3.12 Record Retention

A3.12.1 Retention Periods
A3.12.1.1 Clinical and device records for adult patients shall be retained for at least seven (7) years following device delivery.
A3.12.1.2 Records for paediatric patients shall be retained for at least seven (7) years following the patient's

21st birthday.
A3.12.1.3 Workshop, manufacturing, technical and quality records shall be retained for at least ten (10) years.

A3.12.2 Retrieval Requirements
A3.12.2.1 All records requested by DoH for audit or investigation purposes must be provided within five (5) working days unless a longer timeframe is agreed in writing.

A3.13 Success Indicators (Key Performance Indicators)

A3.13.1 KPI Framework and Targets
A3.13.1.1 Devices delivered within contractual turnaround time target ≥ 95% (measured quarterly).
A3.13.1.2 Claims with invoice and delivery documentation matched target 100% (measured monthly).
A3.13.1.3 Device-related adverse event rate target < 1% per annum (measured annually).
A3.13.1.4 Supplier Technical File completeness compliance target ≥ 95% (measured semi-annually).
A3.13.1.5 Providers purchasing only from ASR-approved suppliers target 100% (measured annually).
A3.13.1.6 Repair turnaround within seven (7) working days target ≥ 90% (measured monthly).
A3.13.1.7 Variance between payer reimbursement and actual cost target ≤ 10% (measured quarterly).
A3.13.1.8 Rework or return rate target ≤ 5% (measured annually).
A3.13.1.9 Turnaround time from prescription acceptance to delivery target defined per device category and measured quarterly.

A3.13.2 KPI Reporting and Publication
A3.13.2.1 Providers and suppliers shall submit KPI data as required by DoH and shall cooperate in data validation activities.
A3.13.2.2 DoH shall maintain and may publish anonymised KPI dashboards to support performance improvement.

A3.14 Enforcement

A3.14.1 Non-Compliance and Sanctions
A3.14.1.1 Non-compliance with any provision of this Appendix constitutes a breach of the DoH DME Policy.
A3.14.1.2 Sanctions available to DoH include written warnings, mandatory CAPA and third-party validation, financial recovery of overpayments, administrative fines, suspension or revocation of licences, delisting from ASR, procurement debarment and referral to legal or professional disciplinary authorities.

A3.14.2 Proportionality and Publication
A3.14.2.1 Sanctions shall be proportionate to the severity, frequency and intent of non-compliance.
A3.14.2.2 DoH may publish de-identified enforcement summaries and trends to encourage sector learning.

A3.15 References

A3.15.1 ISO 13485:2016 + Amendment 1:2024 Medical Devices Quality Management Systems.
A3.15.2 ISO 14971:2019 + Amendment 1:2023 Application of Risk Management to Medical Devices.
A3.15.3 ISO 22523:2021 External Limb Prostheses and Orthoses.
A3.15.4 ISO 10328:2016 Structural Testing of Lower-Limb Prostheses.
A3.15.5 ISO 10993 Series (latest parts 2023–2024) Biological Evaluation of Medical Devices.
A3.15.6 ISO 15223-1:2024 Symbols to be used with information supplied by the manufacturer.
A3.15.7 FDA 21 CFR Part 820 (2024) Quality Management System Regulation (QMSR).
A3.15.8 EU MDR 2017/745 (as amended 2024).
A3.15.9 MOHAP Medical Device Regulation (latest applicable version).
A3.15.10 Applicable national legislation and DoH regulatory instruments.

A3.16 Annexes

A3.16.1 Annex A3.1 Technical File Checklist (referenced in A3.8.2).
A3.16.2 Annex A3.2 Delivery & Fitting Acceptance Note Template (referenced in A3.6.4 and A3.10.1).
A3.16.3 Annex A3.3 Standardized Documentation Checklist (referenced in A3.10.1 and A3.8).

ANNEX A3.1 TECHNICAL FILE CHECKLIST

(Each item required for prefabricated/mass-produced devices; simplified dossier items for custom devices are starred and defined below)

A3.16.1.1 Device identification and UDI/serial.
A3.16.1.2 Regulatory authorisation certificates and registration evidence.
A3.16.1.3 Quality Management System certificate (ISO 13485) and scope.
A3.16.1.4 Risk Management File summary (ISO 14971).
A3.16.1.5 Device technical specifications, design drawings and Bill of Materials.
A3.16.1.6 Material certificates and supplier declarations of conformity.
A3.16.1.7 Mechanical, structural and fatigue test reports (ISO 10328 where applicable).
A3.16.1.8 Biocompatibility test reports or declarations (ISO 10993 parts applicable).
A3.16.1.9 Clinical evaluation summary and evidence supporting intended use.
A3.16.1.10 Instructions for Use and labelling in Arabic and English (ISO 15223-1 compliant).
A3.16.1.11 UDI/serial numbering and traceability procedure.
A3.16.1.12 Manufacturing batch and inspection records.
A3.16.1.13 Approved supplier and subcontractor list with qualification evidence.
A3.16.1.14 Complaint handling procedure and post-market surveillance plan.
A3.16.1.15 CAPA records and vigilance reports.
A3.16.1.16 Warranty, service and spare parts documentation.
A3.16.1.17 Importation records and commercial invoices.
A3.16.1.18 Manufacturer authorisation and representation letters.
A3.16.1.19 Training and competency records for staff.
A3.16.1.20 Change control documentation and version history.
A3.16.1.21 Obsolescence and lifecycle management plan.
A3.16.1.22 Clinical outcome collection plan for novel devices and local data submission timelines.
A3.16.1.23 *Simplified dossier elements for custom devices: design description, material declarations, manufacturing notes, inspection checklist, patient-specific fitting records, and confirmation of clinical oversight.

ANNEX A3.2 DELIVERY & FITTING ACCEPTANCE NOTE TEMPLATE

A3.16.2.1 Patient identifiers (name, MRN).
A3.16.2.2 Prescription reference and prescribing clinician details.
A3.16.2.3 Device category, make, model and UDI/serial.
A3.16.2.4 Workshop/provider name, address and licence number.
A3.16.2.5 Fit and alignment verification fields including objective test results.
A3.16.2.6 Patient education checklist including wear schedule, skin inspection, cleaning and red-flag information.
A3.16.2.7 Confirmation of OPUS completion where applicable.
A3.16.2.8 Loaner device details where applicable.
A3.16.2.9 Signatures: patient or guardian, prescribing clinician, prosthetist/orthotist and provider representative.
A3.16.2.10 Date and time of delivery.
A3.16.2.11 Agreed adjustment or follow-up plan and contact details.

ANNEX A3.3 STANDARDIZED DOCUMENTATION CHECKLIST

A3.16.3.1 Clinical prescription and clinical justification.
A3.16.3.2 Functional assessment reports and classification scores.
A3.16.3.3 Multidisciplinary review notes where applicable.
A3.16.3.4 Technical specifications and workshop fabrication records.
A3.16.3.5 Delivery and Fitting Acceptance Note (Annex A3.2).
A3.16.3.6 Supplier commercial invoice and procurement documents.
A3.16.3.7 Maintenance and repair documentation.
A3.16.3.8 Adverse event reports and CAPA records.
A3.16.3.9 OPUS or equivalent outcome measures.
A3.16.3.10 Traceability records linking device to patient.

TABLE OF ABBREVIATIONS

Abbreviation	Full Term
AFO	Ankle Foot Orthosis
ASR	Approved Supplier Register
BOM	Bill of Materials
CAPA	Corrective and Preventive Action
DME	Durable Medical Equipment
DoH	Department of Health – Abu Dhabi
FDA	Food and Drug Administration
FSN	Field Safety Notice
HCPCS	Healthcare Common Procedure Coding System
ICD	International Classification of Diseases
ICF	International Classification of Functioning
IFU	Instructions for Use
ISO	International Organization for Standardization

Abbreviation	Full Term
K-Level	Medicare Functional Classification Level
MDR	Medical Device Regulation
MOHAP	Ministry of Health and Prevention
MRN	Medical Record Number
O&P	Orthotics and Prosthetics
OPUS	Orthotics and Prosthetics Users Survey
PMS	Post-Market Surveillance
QMS	Quality Management System
QMSR	Quality Management System Regulation (FDA)
SLA	Service Level Agreement
TPA	Third-Party Administrator
TCO	Total Cost of Ownership
UDI	Unique Device Identification