

Intravenous medicines and fluids policy

Document control

Version 2.5 FINAL, updated 23 October 2026; supersedes v2.4. Owner: Dr Mitesh Parmar, Clinical Director, GMC 6113670. Home IV saline pathway approved by Dr Mitesh Parmar, 23 October 2026. Approval lineage: 22 October 2026; service operating since May 2024. Signed records remain in the clinic governance file. Review due 22 October 2027 or sooner after a relevant change.

Clinique Alpha | 466 Green Lanes, Palmers Green, London N13 5PA. Applies with CA-CLIN-SOP-IV-002 (preparation), CA-CLIN-SOP-IV-003 (adverse events and aftercare) and CA-CLIN-SOP-IV-004 (procurement and recalls).

1. Purpose and confirmed service scope

Version 2.5 adds a home IV saline pathway (IV-002 section 16): sodium chloride 0.9% from a ready-to-administer bag, nothing added, given at home by Dr Parmar or Dr Alpa. IV iron and IV vitamin C remain clinic only. IV-002, IV-003 and IV-004 are v1.4. Earlier issues remain history; replace current links at the existing policy page.

Scope: planned treatment of adults aged 18 and over at the Palmers Green clinic, comprising IV fluids, IV iron and any approved standalone vitamin C pathway, plus IV sodium chloride 0.9% in the patient's home under IV-002 section 16. IV iron and IV vitamin C are given at the clinic only. Multi-ingredient formulas were withdrawn in October 2026. Excluded: paediatric care, home infusion of any medicine or of any fluid other than ready-to-administer sodium chloride 0.9%, any addition, mixing or preparation in a home, emergency resuscitation as a planned service, blood products, parenteral nutrition, chemotherapy, multi-ingredient wellness cocktails and IM injections. No advance preparation, batch production for anticipated demand, custom pharmacy-compounded bags or sale of prepared bags is authorised. Any extension requires separate clinical and medicines risk assessment. Emergency response to a complication remains mandatory.

2. Clinical decision and consent

A GMC-registered prescribing doctor must assess the individual patient, establish a documented clinical rationale and consider oral treatment, usual care or no intervention. Booking or payment does not guarantee an infusion. Review relevant diagnoses, medicines, allergies, previous infusion reactions and the investigations needed for the selected treatment. A requested wellness treatment is not itself evidence of benefit or justification for IV administration.

Discuss expected benefit, uncertainty, alternatives, material risks, follow-up and costs through the clinic's normal consent process. Explain relevant off-label or unlicensed use and document the rationale and information given. Take responsibility for monitoring and follow-up. A signature does not replace an informed discussion. [R06]

3. Approval and operational status

The IV service has operated since May 2024. Dr Parmar and Dr Alpa prepare/administer in rooms 1 and 3. Training and room assessments were completed on 22 October 2026. On 23 October Dr Parmar confirmed that the supporting training/competency records, room assessments and product approvals are complete and signed. Retain the original records and their actual dates privately; no new signatures or test results are created by this policy. Dr Parmar confirmed on 23 October 2026 that the clinic gives IV sodium chloride 0.9% at home (Dr Parmar and Dr Alpa only; IV-002 section 16). No home assessments or home start date are recorded here; the 22 October 2026 IV and resuscitation training applies.

Responsibilities and applicable standards

4. Roles and accountability

Role	Required responsibility
Clinical Director	Approve scope, product profiles, staff authorisations, premises assessment, emergency and aftercare arrangements; review incidents and audit findings; authorise changes.
Reviewing / prescribing doctor	Dr Alpa Morawala or Dr Mitesh Parmar reviews and authorises treatment. Assess and prescribe for the patient; verify indication, dose, preparation and follow-up; remain accessible for clinical decisions.
Authorised preparer/administrator	Dr Mitesh Parmar and Dr Alpa Morawala prepare and administer. Work within competence, patient-specific authority and the approved protocol; record checks, preparation, observations and escalation. For home IV saline, the treating doctor checks the home setting, carries the checked emergency kit, stays with the patient and shares visit details before each visit (IV-002 section 16; IV-003 section 1).
Pharmacist / medicines adviser	Provide specialist advice when the product risk assessment identifies a need. Joint pharmacist/senior-clinician assessment is SPS best practice; doctor review is not pharmacist review. See section 6.
Clinic manager / infection-control lead	Maintain cleaning, stock, equipment, training, controlled documents and emergency arrangements, with named cover for absence.
Stock/alerts lead and deputy	Dr Parmar, Dr Alpa and Dr Amit check daily and cross-cover. The weekly rota names a lead and deputy. The lead records relevance, action ownership, deadlines and closure; Dr Parmar retains overall accountability.
All staff	Recognise urgent concerns, route them promptly to clinical staff, protect confidentiality and report incidents; do not give advice beyond competence.

5. Legal framework and preparation setting

CQC Regulation 12 requires safe care, risk management, competent staff, appropriate premises/equipment, medicines management and infection control. Regulation 17 requires effective governance and accurate records. These duties apply to this England-based clinic; registration is not approval of an individual mixture. [R01-R02]

The Human Medicines Regulations contain conditional exemptions relevant to doctor preparation and specified patient-specific mixing. Record the lawful basis for the actual activity; a wholesale licence, prescriber status or exemption does not by itself establish a preparation's quality or safety. [R04-R05]

For routine clinical-area preparation, select a method for immediate administration supported by the actual product's instructions. Under this clinic SOP, preparation outside those instructions, or for later storage, must be referred to an appropriate pharmacy aseptic service or supplier for assessment and supply; advice alone does not authorise that clinic preparation. An off-label clinical indication is not automatically a deviation from the preparation method. [R07-R08]

QAAPS/pharmacy aseptic-service requirements and manufacturing GMP standards have their own scope. They are not interchangeable with a clean clinical preparation area. GPhC pharmacy standards apply to relevant pharmacy partners; this clinic is not described as a pharmacy. [R11, R30]

Product approval, staffing and assurance

6. Product and process authorisation

Dr Mitesh Parmar and Dr Alpa Morawala both sign each product/process approval against the current SmPC and preparation risk assessment. Either doctor may review/prescribe for an individual patient and check supplier batches/expiry. Record indication, preparation, monitoring, use period, restrictions and review triggers in IV-002. A second doctor checks each preparation when present; record who checked. If the product assessment requires a second check, obtain it before administration.

SPS recommends a pharmacist and senior clinician assess preparation risks as best practice. This policy uses documented doctor-led review for the clinic pathway; record the rationale and residual risks if pharmacy input is not obtained. Seek appropriate specialist advice for uncertainty over compatibility, stability, supply or preparation, or risks beyond the doctors' competence. Resolve safety concerns before use. This is not a blanket legal exemption or a completed pharmacist review. [R08]

7. Staff, environment and emergency readiness

Dr Parmar and Dr Alpa have relevant hospital and IV experience. IV/refresher and resuscitation training was completed on 22 October 2026; Dr Parmar confirms the supporting training/competency records are completed and signed. Retain task-specific evidence for calculation, asepsis, cannulation, monitoring, emergencies and records. Maintain annual resuscitation training and reassess other skills after a lapse, incident or change.

Rooms 1 and 3 are used. Their suitability assessments were completed on 22 October 2026, with signed records confirmed retained. Review changes and check the actual surface, cleaning, equipment and emergency arrangements before each session. Staff treatment and observation safely and use IV-003 for contact and escalation, including Saturday closure. Home IV saline: before cannulation the treating doctor checks the home setting under IV-002 section 16; if it is unsuitable, treatment does not go ahead.

8. Local audit and review programme

Retained clinic standard: review the first five cases after operational release or a material change, then quarterly review all cases if fewer than ten, or a sample of at least ten cases, as required by v1.0. Audit patient-specific prescribing and consent; product/batch traceability; correct preparation and timing; observation; aftercare; and completion of follow-up. Review every serious incident and each recall action. These are retained local requirements, not statutory quotas. Target 100% compliance for prescription, assessment/consent, traceability/preparation and observation/discharge; every deviation needs an owner, due date and closure review. Home saline infusions are included in this audit programme.

Track deficiencies and corrective actions. Include batch-to-patient linkage in routine record audits and review failures, recalls and record-system changes. Use a practical retrieval exercise when needed to establish reliability; no fixed annual mock-recall test is a release condition. No completed mock test is claimed. Allergy checks do not replace recall tracing. Suspend an unsafe affected process and arrange onward care.

9. Document and website control

Keep one approved master and a revision log. Retain superseded versions marked as historical. Review this package annually and sooner when warranted. Keep service pages consistent with the approved scope; preserve the current removal of withdrawn treatments. Publish only the approved version and describe only verified operating controls. CQC, MHRA and source references do not endorse this clinic or guarantee certification.

Confirmed practice and controlled records

10. Confirmed clinic arrangements

Item	Confirmed arrangement / record
Service	Operating since May 2024; adults; clinic, plus home IV saline only; no multi-ingredient formulas. Home IV saline pathway approved 23 October 2026. Updated 23 October 2026.
Products and supply	Venofer [R37]; Ascorbic Acid Pascoe 150 mg/ml, PL 14369/0009 [R23]; Ecoflac saline supplied by AAH. Exact container/label details are retained in stock records.
Signed records	Dr Parmar confirms training/competency, rooms 1 and 3 assessments and product approvals complete and signed. Training/room assessments: 22 October 2026.
Traceability	Each component batch/expiry is linked to the patient infusion. Supplier checks apply. Risk-based assurance; no mock-recall pass claimed. Home saline: bag and giving set batch/expiry recorded at the visit.
Aftercare	Mon-Fri 09:00-20:00; Sun 09:30-17:30. Saturday closed: NHS 111/999. Other out-of-hours diversion: Dr Parmar/Dr Alpa; response not guaranteed.
Alerts	Direct MHRA/GOV.UK alerts to enquiries@cliniquealpa.co.uk are active and distributed to clinicians. CAS also arrives via Dr Parmar's NHSmail and is forwarded. Daily checks; weekly lead/deputy.

Document authority - Approval lineage: 22 October 2026; consolidated final issue: 23 October 2026.

Service and review - Service since May 2024. Next review 22 October 2027.

Private evidence index - Reference the completed signed approvals, competence/training and room records:

11. Sources and scope of evidence

Product references checked 23 October 2026. Confirm current product instructions at review and for any change. Pascoe and Ecoflac supply are confirmed; record exact saline strength, volume and licence from the stock label. The B. Braun source is a reference for matching the actual presentation [R38].

- R01. CQC: Regulation 12 - safe care and treatment
- R02. CQC: Regulation 17 - good governance
- R04. Human Medicines Regulations 2012: regulation 3
- R05. Human Medicines Regulations 2012: regulation 20
- R06. GMC: prescribing unlicensed medicines
- R07. NHS SPS: aseptic manipulation of injectable medicines
- R08. NHS SPS: assessing risks when reconstituting injectable medicines
- R11. MHRA: good manufacturing and distribution practice
- R23. Ascorbic Acid Pascoe: UK SmPC - confirmed clinic vitamin C product
- R37. Venofer: UK SmPC - confirmed clinic iron product
- R38. B. Braun sodium chloride 0.9% IV infusion: SmPC - match the actual stock label

Implementation records and session checks

12. Implementation and records

- Keep service history separate from document issue dates: May 2024 is the service commencement, not approval of later policies.
- Dr Parmar confirms completed, signed product/process approvals by both doctors. Retain the current SmPC, preparation risk assessment, monitoring, restrictions and any specialist advice; review material changes.
- Training/competency and room-assessment records are confirmed complete and signed. Retain the original assessor, scope, findings and dates. Training and room assessments were completed on 22 October 2026.
- Maintain consent, emergency/extravasation and infection-control procedures, equipment checks and patient aftercare. Keep personal contacts and call-routing records privately.
- Operate the active direct MHRA inbox and the additional CAS NHSmail forwarding route. Use the weekly lead/deputy rota, daily checking, named actions and cross-cover; preserve the actual delivery settings.
- Maintain patient-linked batch records and proportionate traceability assurance. No mock-recall or phone-test result is inferred from signed training or product approvals. Check safety before every treatment.

13. Session release

Before each treatment verify identity, current assessment/results/medicines/allergies, approved product protocol and prescription, consent, staff and emergency cover, intact products and traceable batches, required checks and label, cannulation and baseline observations, monitoring, post-treatment observation, aftercare and follow-up. Use the IV-002 administration record; a previous signature does not waive reassessment. For home IV saline, also confirm the home setting check, a complete in-date emergency kit and that visit details were shared; otherwise treatment does not go ahead.

Product/process records - Reference the signed two-doctor approvals, current SmPCs and risk assessments:

Implementation records - Location of completed competence/training and room-assessment records; subsequent actions:

Controlled master - Current issue 23 October 2026; next review 22 October 2027:

Version history and confirmed practice

v2.5 / SOPs v1.4: Home IV saline pathway approved by Dr Mitesh Parmar, 23 October 2026.

Issue / change	Disposition in this revision
v0.1 / v1.0, 20 October 2026	Initial draft; then v1.0 approved by Dr Parmar. Operational release remained separate. Historical baseline retained.
v2.0, 22 October 2026	FINAL, approved by Dr Parmar on 22 October 2026; supersedes v1.0. Operational release remains separate. Publish at the existing canonical page.
v2.1 / SOPs v1.1, 22 October 2026	FINAL update authorised by Dr Parmar. Adds Venofer/SmPC, named clinical reviewers/authorisers and confirmed patient-linked batch/expiry records. Other release checks stay separate.
v2.2 / SOPs v1.2, 23 October 2026	Names preparers, rooms, training/assessment dates, contacts and alerts. Two-doctor product approval; pharmacy advice by risk. Removes mandatory annual mock test; retains tracing and assurance.
v2.5 / SOPs v1.4, 23 October 2026	Adds home IV saline (sodium chloride 0.9% only) by Dr Parmar or Dr Alpa; iron and vitamin C clinic only.
Document structure	Preparation, adverse events and supply/recall detail moved into subordinate IV-002, IV-003 and IV-004 v1.0; no competing governance policy.
Scope and review controls	Adult-only scope, observations, weekly equipment checks, annual resuscitation training and first-five/quarterly-ten audit retained. Earlier blanket pharmacy condition revised in v2.2.
USP and timing	Added qualified distinction between administration, preparation per approved labelling and immediate-use CSPs. Four hours concerns starting administration, not shelf life. No four-hour storage rule existed in the inspected v1.0.
Vitamin C / preparation	Added documented laboratory G6PD-result review before proposed high-dose treatment, explicit glass-ampoule particulate filtration and clearer product timing/traceability forms. Actual product protocol remains essential.
Iron safety	Retained hypersensitivity exclusions, no routine initial test dose, at least 30-minute observation and phosphate precautions. Clarified potentially permanent staining and the need for accurate product-specific adverse-effect information.
Aftercare and reporting	Expanded delayed-event triage, actual contact-cover requirements, patient leaflet and record; clarified independent-provider candour and separate CQC notifications.
Procurement / recalls	Supplier/manufacture checks, patient batch linkage, alerts and recall action retained. Earlier annual mock test replaced by risk-based assurance in v2.2.
Status and evidence	Added consolidated confirmation register and 12-question evidence map. No claim of ISO facilities, USP compliance, specific supplier/product use or 24-hour cover without evidence.

SPS joint pharmacist/clinical risk assessment remains recommended best practice. Signed clinic records are confirmed by Dr Parmar and retained privately. Doctor review is not pharmacist review; no mock-recall or phone-test pass is claimed. Review due 22 October 2027.