SCHEDULE 2 – THE SERVICES

A. Service specifications

1. Service name	Specialist services for haemophilia and related bleeding disorders (adults and children)
2. Service specification number	• xxxxxxxxx
3. Date published	• xx/xxxx/2025
4. Accountable Commissioners	NHS England • Specialised Blood Disorders Clinical Reference Group • Blood and Infectious Diseases National Programme of Care Board: Blood and infection england.npoc-bloodandinfection@nhs.net

5. Population and/or geography to be served
5.1 Population covered
All ages
5.2 Minimum population size
The service specification is applicable to the provider recognised as haemophilia comprehensive care centres (CCC) or haemophilia treatment centres (HC). CCC will typically manage at least 40 service users with severe haemophilia as well as many more service users with other bleeding disorders, inherited and acquired, and non-severe presentations. There is a network of over 20 CCC across England, with a similar number of smaller HC services.

6. Service aims and outcomes
6.1 Service aims
• reduce mortality and morbidity in service users

- deliver multidisciplinary specialist care to people of all ages living with bleeding disorders including congenital and acquired haemophilia, von Willebrand disorder, other factor deficiencies, platelet function disorders, and bleeding disorders of unknown cause
- enable service users to lead as fulfilling a life as possible and to actively engage and participate in all areas of life and society
- enable those with related and general comorbidities to optimise life-long functioning, resilience, general and mental health
- provide diagnoses, treatment, and advice to service users and family members

6.2 Outcomes

NHS outcomes framework domains and indicators

Domain 1	Preventing people from dying prematurely.
Domain 2	Enhancing quality of life for people with long-term conditions.
Domain 3	Helping people to recover from episodes of ill health or following injury.
Domain 4	Ensuring people have a positive experience of care.
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm.

Service defined outcomes/outputs

- For long-term or life-long bleeding disorders
  - annualised bleeding rates (ABR), differentiated between joint bleeds and other types of bleed
  - measures of functional joint damage and activities of daily living as recommended by the Haemophilia Chartered Physiotherapist's Association (HCPA) [Expected to be published later in 2025 on www.ukhcdo.org/haemophilia-associations/physiotherapy-information/]
  - measures of quality of life and psychological health and wellbeing as recommended by the Haemophilia Psychology Association (HPA).
- For all specialised bleeding disorders including inherited, acute and acquired bleeding disorders
  - mortality rates and mortality metrics (ie age and cause of death).

The provider must ensure standards in the most recent periodic United Kingdom Haemophilia Centre Doctors' Organisation (UKHCDO) national peer review and audit are achieved by all audited centres.

Providers, in conjunction with commissioners and their clinical teams, must deliberate on peer review findings and give favourable consideration to implementing the changes identified with a view to ensuring comprehensive, safe,

care. In the case of non-compliance with standards, The provider must agree remedial action plans with commissioners in respect of the UKHCDO peer review and audit.

The provider must ensure complete, accurate and timely returns to the National Haemophilia Database.

7. Service description

7.1 Service model

Scope

Specialised bleeding disorders within the scope of this specification include:

- inherited bleeding disorders such as haemophilia A, haemophilia B, von Willebrand disorder, and platelet function defect
- other rare inherited bleeding disorders and bleeding disorders of unknown cause
- acquired bleeding disorders such as acquired haemophilia A

The following disorders that may result in bleeding are not included within the scope of this specification:

- immune thrombocytopenia purpura (ITP)
- thrombotic thrombocytopenic purpura (TTP)
- hereditary haemorrhagic telangiectasia (HHT)
- bleeding secondary to
    - liver disease
    - disseminated intravascular coagulation
    - anticoagulation, antiplatelets, and fibrinolytic therapies
    - collagen disorders such as Ehler-Danlos syndrome and joint hypermobility
- the management of traumatic, obstetric or surgical bleeding episodes
- other general haemostasis and thrombosis services

Diagnosis and referral

Bleeding disorders have historically been defined based on biochemical measures of coagulation factor activity into severe, moderate and mild disorders. However phenotypic classification based on the actual presentation of the service user should be preferred in treatment strategies. Persons related to service users may also have genetic changes which lead to increased bleeding tendency and be diagnosed as having a bleeding disorder. Even where there are no symptoms, relatives and others may be diagnosed as ‘carriers’ of genetic traits with a potential for bleeding disorders.

The provider will be differentiated between a CCC and an HC.

General

The needs, priorities and preferences of service users and their families will vary at different times over the course of their lives. It is essential that services maintain

lifelong contact with affected persons, subject to trust policy, even during prolonged periods of reduced care demand. All service users with a severe or moderate disorder, and those on regular prophylaxis treatment, must be routinely offered regular clinical reviews, including an in-person comprehensive clinical review with a CCC service, at least once a year:

- every 6 months for adults
- paediatric service users may need more frequent reviews than adults, up to 4 times a year

Other users, and intermediate reviews, may be served by remote contact.

Service users must be under the care of a haematology specialist with expertise and an interest in haemostasis and bleeding disorders.

Service users on long-term treatment will usually receive their treatments via a home delivery or home-care arrangement arranged by their clinical team.

Some treatments and services are available only from specific providers. For example, a limited number of CCC provide gene therapies for haemophilia and related disorders. Other treatments may only be accessed via a CCC (see NHS England's high cost drugs commissioning list).

Service users should have access to outreach support when necessary, including for support and education of carers (parents/school/residential and nursing homes) and for home visits to support care if required, for example young children, people with disabilities, people with additional care needs. Outreach will also include training for intravenous infusions and use of portacaths.

The UK is an active environment in clinical research for haemophilia and related disorders. All eligible service users should be offered opportunities to participate in clinical trials including referral to other providers to enable participation.

CCCs must provide regular multidisciplinary team (MDT) meetings and include other providers within their catchment where appropriate.

Paediatric care

Most CCC will also provide care for paediatric service users. In some localities a dedicated paediatric CCC will be based at a Children's Hospital. Paediatric services must be led by a paediatric haematologist with a specialist interest in haemophilia and bleeding disorders **or** jointly by a paediatrician and a haematologist who specialises in haemophilia and bleeding disorders. Other MDT care, for example nurses, physiotherapists and psychologists, must be provided by those with experience of providing paediatric care.

Special requirements of paediatric care include, but are not limited to:

- training third parties (eg parents, carers, other household members) to recognise bleeds and administer treatment(s)
- at the appropriate time, based in part on service user age and maturity, to train paediatric service users to administer their treatment(s)
- liaising with schools and other community-based institutions (eg clubs, societies) to educate and train responsible adults in looking after children living with a bleeding disorder
- access to the insertion and care of indwelling catheters

The care environment must be suitable and appropriate for the age and developmental status of the paediatric service user in dedicated paediatric facilities.

Paediatric service users may need frequent adjustments to the dose of treatment(s) for haemophilia or bleeding disorder reflecting periods of rapid growth and changes in behaviour or physical activity. Paediatric service users with severe bleeding phenotypes and those on prophylaxis should be reviewed by the CCC at least 4 times a year until an appropriate point has been reached when review frequency can step down to every 6 months.

Services will need to engage with paediatric service users in a collaborative manner to ensure that treatment adherence is maintained as service users assume responsibility for their own treatment. Paediatric service users will need specific care and support relating to menarche.

Planning should take place with a paediatric provider for the management of fetuses and neonates with an antenatal diagnosis, or known to be at risk, of haemophilia and other bleeding disorders.

Transfer planning will take place between the paediatric and adult provider to ensure a smooth transition to adult care for adolescents (see also 7.2).

Nursing care

Service users must have access to specialist nurses trained in line with the Haemophilia Nurses Association (HNA-UK) [expected to be published later in 2025 on www.ukhcdo.org].

Services must aspire to the staff development pathway for specialist haemophilia nurses.

Physiotherapy

People living with bleeding disorders require specialist physiotherapy care to help them live well, manage acute joint bleeds, chronic arthropathy, prevention of joint and muscle bleeds, rehabilitation after surgery, and help prevent disability. Service standards are defined by the HCPA and UKHCDO, and the provider must deliver these standards. [expected to be published later in 2025 on www.ukhcdo.org/haemophilia-associations/physiotherapy-information/]

Service users must have rapid access to a dedicated physiotherapy service, including self-referral, with specialist physiotherapists trained in line with the HCPA standards of care. Physiotherapists will link with occupational therapy services and podiatry services where these interventions are required.

Services must aspire to the staff development pathway for specialist haemophilia physiotherapists.

Psychology

Those responsible for psychological care have a vital role to play in supporting individuals in their treatment, decision-making, and in maximising self-management and independence.

A legacy of the historical use of infected blood and blood products means that many people living with bleeding disorders and their families have unique and challenging psychological needs.

Service users, including carers and families, must have access to dedicated psychological support. Service standards for specialist psychological support are defined by the HPA and the provider must deliver these standards.

Social and care

Service users must have access to social and care workers. Services should host social and care workers, and related roles, with dedicated resource to work within specialised bleeding disorder and haemophilia services. Roles include:

- promote service user and carer rights and advocate on behalf of people living with bleeding disorders and family
- act as safeguarding liaison and champions
- participate in MDT meetings
- enable disadvantaged service users to optimise health outcomes, eg refugees and asylum applicants
- ensure adherence to relevant legislation
- provide financial advice and help to navigate the welfare system

Social workers adhere to a professional Code of Practice as outlined in the Care Act (2014).

Dentistry and dental services

It is essential that haemophilia services liaise with local dental practices, and that CCC have access to hospital-based dental and maxillofacial care for the most complex dental cases.

People living with bleeding disorders require a comprehensive treatment plan with an overall goal of achieving haemostasis when a dental procedure is required. Such plans must be agreed with the service user. Treatment plans should be in place for elective and emergency episodes of dental care.

Pregnancy and fetal medicine

Pregnancy planning should be discussed pre-conception with persons living with a bleeding disorder or those at known risk of conceiving a child with an inherited bleeding disorder as they require specialist advice regarding contraception, pregnancy, and delivery.

Service users and their partners should be offered pre-implantation genetic diagnosis in accordance with agreed policies.

Persons living with a bleeding disorder must be referred to maternity services immediately once a pregnancy is confirmed. Haemophilia services must liaise with maternity, neonatal, and paediatric services where a pregnancy involves 1 or more babies with likely or suspected diagnosis of a congenital bleeding disorder. Pregnancy care will be planned early on in pregnancy and may require access to fetal sexing, antenatal diagnosis, termination of pregnancy services, and diagnostic amniocentesis, if appropriate.

Pregnant persons must be counselled on the additional care needs, risks, tests, and treatments which may be required before, during and after giving birth. An individualised care plan for any pregnancy affected by a bleeding disorder must cover the ante-natal, intrapartum and postnatal periods. Plans must include clear instructions for shared care with secondary services including escalation and transfer protocols, and clear instructions for planned and emergency delivery.

Management of pregnancy and the neonate should follow guidelines on the Management of inherited bleeding disorders in pregnancy, published by the Royal College of Obstetricians and Gynaecologists.

Obstetrics and gynaecology

Many women, girls and people with the potential to menstruate (WGPPM) diagnosed with a bleeding disorder will experience heavy menstrual bleeding and they should be able to access specialist gynaecology advice and associated care.

A written 'management of menstruation plan' that is co-produced with the service user should be provided prior to menarche. Younger WGPPM living with bleeding disorders may first present to services when menstruation commences.

WGPPM with a history which suggests an inherited bleeding disorder should be fully investigated for an inherited bleeding disorder.

Pharmacy

Provider pharmacy departments will be responsible for procurement of medicines from national frameworks where available. Clinical pharmacists with expertise in haematology should support and assist in medication reviews, optimising value from prescribing, service user training and education in relation to prescribed treatments, medication access and rotation amongst local clinical networks, and homecare governance.

Laboratory services

CCCs must have a co-located accredited laboratory service capable of the diagnosis and monitoring of treatment in all bleeding disorders. All services must provide a routine laboratory service during normal working hours plus specialist on-call cover and urgent haemostasis laboratory tests at other times.
See section 7.5.

Data reporting

CCCs and HCs must report service user metrics to the National Haemophilia Database (NHD) on a regular basis and in accordance with the agreed consent process at that time.

Haemophilia services should have dedicated data administrators to facilitate NHD reporting and other departmental functions to free up resource for clinical care. Haemophilia services should empower and enable eligible service users to access and share treatment metrics and sequelae through digital platforms.

Other services for co-ordinated care

- Rheumatology and orthopaedics due to cumulative arthritic joint damage.
- Infectious diseases including HIV and viral hepatitis.
- Pain Management.
- Hepatology.

- Laboratory genetic services.

7.2 Pathways

Overall service user pathway

Service user referrals and diagnoses arise through different routes, with most via one of the following:

- prospective screening of individuals through familial case-tracking
- newborn or antenatal screening programmes
- unexplained or excessive bleeding episodes, often identified or observed
    - in general practice
    - gynaecological services
    - surgery
    - referred from child protection services or similar
    - emergency departments
- acute and often life-threatening bleeding episodes via emergency admissions; these may occur at any NHS provider

Specialised service user pathway

Management of all aspects of the bleeding disorder should be provided through a combination of outpatient clinics for routine reviews and open access to the CCC/HC, with dedicated space for more acute issues. Standards of care for emergency and out-of-hours care for service users with bleeding disorders should be followed. All service users must have 24-hour 7-days a week access to the expertise of a CCC although some services will be delivered at a HC in collaboration with a CCC through a network arrangement. HCs should have links with a CCC for 24/7 access to advice and shared management.

In addition to the standard referral pathway to a CCC, referrals may arise directly from the relatives of affected service users.

Routine clinics to review the management of bleeding disorders should be offered to all service users, should be multidisciplinary, and offer access to medical, nursing, physiotherapy, and psychology clinicians with expertise in inherited bleeding disorders.

Clinics may be in person or remote (eg video or telephone) based on clinical and social circumstances, and user preference. Outreach clinics may be offered at hospitals closer to the service user's home. Service users with a severe and moderate bleeding phenotype and those on prophylaxis should have a review at least every 6 months including an in-person comprehensive clinical review with a CCC at least once a year. Other service users should be reviewed as clinically indicated and referred for advice and support from multidisciplinary team members if needs are identified. Contact must be maintained with all service users irrespective of burden of disease.

Every service user must be offered a bleeding disorder information 'card', either electronic or paper or both, which will include details of their condition, usual

treatment, treatment centre and out-of-hours contact details for the haemophilia service.

Service users should be supported in home treatment and educated in the self-management of their bleeding disorder. A home therapy programme should support home treatment for relevant service users across the network including the administration of prophylactic therapy, home and school visits, and residential or nursing home visits where appropriate; and MDT outreach clinic review near or at home for those with additional needs.

Service users must be encouraged to use prophylactic treatment regimens according to agreed UK guidelines. Immune tolerance should be offered according to UKHCDO guidelines and agreed clinical policies.

Service users with an acute bleeding episode or who experience complications of their bleeding disorder must have access to multidisciplinary care including specialised medical, nursing, and physiotherapy care.

Major surgery should only occur where the haemophilia service can fully support the service user. Invasive procedures for service users with an inhibitor must be undertaken at a CCC with expertise in management of such cases. A written treatment plan for each procedure should be agreed with the service user and surgical team including anaesthetics.

Service users who may be eligible for advanced therapeutic medicinal products (ATMPs) such as gene therapy for haemophilia A and B, will be managed through CCCs in a hub and spoke network. See UKHCDO guidelines.

Service users have a right to be involved in evidence-informed decisions about their treatment and care. All members of the clinical team should actively promote shared decision making with service users and caregivers, supported by decision aids and decision support counselling, where relevant to ensure individual circumstances remain the focus of care. NICE guideline [NG197].

Shared care arrangements

Bleeding disorders are not suitable for management or shared care with primary care medical services. Primary care services must be aware of diagnoses in people living with bleeding disorders as this will impact on other care provision and prescribing.

Shared care between providers is established in the management of bleeding disorders, especially between HC and a linked CCC (see section 7.3). Shared-care facilitates access to innovative, novel and trial therapies, as well as some treatments which are not universally provided (eg radiosynovectomy).

Trusts that host CCC/HC must accept out of area referrals for procedures that require specialist haemostasis input. This could include invasive dental or surgical procedures, endoscopy and radiology.

Co-ordinated care for rare conditions

Co-ordination of care involves working together across multiple components and processes of care to enable everyone involved in a service user's care (including a team of healthcare professionals, the service user, or carer, and their family) to

avoid duplication and achieve shared outcomes, throughout a service user's whole life, across all parts of the health and care system including:

- care from different healthcare services (eg different medical disciplines – medical, physical, behavioural, dental, health promotion)
- care from different healthcare settings (including secondary and tertiary; community settings, eg social care, dental) and locations
- care across multiple conditions, or single conditions, or single conditions that affect multiple parts of the body
- the movement from one service, or setting, to another

Co-ordination of care should be family-centred, holistic (including a user's medical, psychosocial, educational and vocational needs), evidence-based, with equal access to co-ordinated care irrespective of diagnosis, circumstances and geographical location.

Transition of children and young people moving from children's to adult services

Transfer planning will take place between paediatric and adult services to ensure a structured, developmentally appropriate and person-centred smooth transition to adult care for young people. NICE guideline [NG43].

7.3 Clinical networks

The provider is required to participate in a networked model of care to enable services to be delivered as part of a co-ordinated, combined whole system approach.

Managed multidisciplinary clinical networks are provided by a CCC within their local catchments. Networks should be appropriately resourced, both clinically and in terms of administrative support. Network activities include, but are not limited to:

- outreach or supported clinical reviews closer to the service user's home
- defining and implementing policies and pathways for local practice
- MDT open to all relevant parties including local clinicians
- dedicated medication stock holding and rotation
- reporting of all cases to the NHD and other submissions to the NHD
- access to novel and innovative treatments
- widening service user access to clinical research trials
- clinical education and training
- sharing best practice, intelligence, and infrastructure

Networks should include service user views in their discussions.

7.4 Essential staff groups

- Haematology specialists with expertise in bleeding disorders, demonstrated by membership of UKHCDO and participation in relevant continuous professional development, education and training.
- Paediatric haematologist with a specialist interest in haemophilia and bleeding disorders **or** joint oversight by a paediatrician **and** a haematologist who specialises in haemophilia and bleeding disorders.

- Specialist haemophilia nurses.
- Specialist haemophilia physiotherapists (www.ukhcdo.org/haemophilia-associations/physiotherapy-information/).
- Practitioner psychologist or psychotherapist with specialist knowledge of bleeding disorders (www.ukhcdo.org/haemophilia-associations/psychology-information/).
- Administrative support.
- Centre manager (CCC).
- Data manager or similar (CCC).
- Biomedical Scientists specialised within haemostasis.

7.5 Essential equipment and/or facilities

CCCs must have access to suitable age-appropriate space and facilities to review and clinically manage service users and their families. This will extend to outpatient clinics, walk-in, open-access and treatment areas, access to inpatient beds including intensive care, radiology services, surgical services, facilities for physiotherapy assessments, and dedicated staff office space. HCs will often incorporate care of haemophilia and other bleeding disorders within general haematology facilities.

Haemophilia services must have access to radiosynovectomy expertise and procedures which have historically been available at a small number of providers within England. Therefore, in most cases, access to radiosynovectomy will require referral to an appropriate CCC.

Comprehensive care centres must provide a United Kingdom Accreditation Service (UKAS) accredited laboratory service capable of the diagnosis and monitoring of treatment in bleeding disorders. Each laboratory must have its own laboratory handbook dictating test repertoire and turnaround times.

Haemophilia and bleeding disorder services must have a UKAS accredited specialist haemostasis laboratory service capable of carrying out tests necessary for the definitive diagnosis of inherited and acquired bleeding disorders, including the identification and assay of the relevant specific haemostatic factors. The specialist haemostasis laboratory must maintain satisfactory quality control and assurance for all laboratory tests offered in relation to clinical services, both by establishing the appropriate level in the UK National External Quality Assessment Scheme in Blood coagulation (NEQAS), or other relevant approved external quality assessment schemes.

The specialist haemostasis laboratory should provide all relevant tests during normal working hours, and additionally provide an out-of-hours service for critical assays such as factor VIII, factor IX, and von Willebrand factor. Laboratories must be capable of monitoring therapy and screening for inhibitors with quantification of any inhibitor detected in accordance with published UKHCDO guidelines. Laboratory services should also support analysis and identification of atypical cases, diagnosis of hereditary platelet disorders and access to molecular diagnostic testing through a molecular genetic hub (and participate in regional molecular genetics MDT).

As the majority of cases within haemophilia and specialised bleeding disorders have an inherited origin it is essential that haemophilia services link closely with the regional NHS genomic laboratory hubs and access genomic MDTs. Multiple genomic tests are available for inherited bleeding disorders.

7.6 Interdependant service components – links with other NHS services

All staff working in haemophilia and related services who are in direct contact with patients and other service users should be aware of the Infected Blood Inquiry: the report and its consequences, and recognise the impact it may have on specific groups or individuals.

7.7 Additional requirements

None

7.8 Commissioned providers

The list of commissioned providers for the services covered by this specification is available from the responsible commissioner(s).

7.9 Links to other key documents

Refer to the Prescribed specialised services manual for information on how the services covered by this specification are commissioned and contracted for.

Refer to the Identification rules tool for information on how the activity associated with the service is identified and paid for.

Please check for more recent versions of any sources included herein.

Refer to the relevant Clinical Reference Group webpages for NHS England commissioning policies which define access to a service for a particular group of service users. The specific clinical policies that relate to the services covered by this service specification include (August 2023):

- susoctocog alfa for acquired haemophilia A
- human coagulation factor X for hereditary factor X deficiency (all ages)
- emicizumab as prophylaxis in people with congenital haemophilia A with factor VIII inhibitors (dosing instructions)
- emicizumab as prophylaxis in people with severe congenital haemophilia A without factor VIII inhibitors (all ages) (dosing instructions)
- the use of rituximab as a second line agent for the eradication of inhibitors in patients with acquired haemophilia
- immune tolerance induction (ITI) for haemophilia A (all ages)
- vonicog alfa for the treatment and prevention of bleeding in adults with von Willebrand disease

In addition, access to other blood factors and related products has been determined by guidelines issued by the British Society for Haematology (BSH). These guidelines can be found on the BSH website; where there is an NHS England clinical commissioning policy for the same indication, the policy is

definitive. For example, The use of prophylactic factor replacement for children and adults with haemophilia A and B, British Society for Haematology, 2020.

Agreed criteria to access enhanced half-life factor products are addressed in the NHS England high cost drugs commissioning list.

Emergency and out-of-hours care for patients with bleeding disorders – standards of care for assessment and treatment. UKHCDO, 2009

Management of inherited bleeding disorders in pregnancy guideline published by the Royal College of Obstetricians and Gynaecologists.

Shared decision making, NICE guideline [NG197], June 2021

Supported self-management, summary guide. NHS England, 2020

Transition from children's to adults' services for young people using health or social care services. NICE guideline [NG43], 2016