NHS National Services Scotland

Service Agreement with NHS Greater Glasgow and Clyde

Inherited Metabolic Diseases (all ages)

Specialist Service

1 April 2022 to 31 March 2025

Service Agreement – IMD Service

1. Terms of Service Agreement

The purpose of this agreement is to set out the commissioner / provider service arrangements between National Services Division (NSD) and NHS Greater Glasgow & Clyde (GG&C) for the delivery of the nationally designated Inherited Metabolic Disorders service. In the context of this agreement, NSD is the Commissioner and NHS GG&C is the Provider.

This agreement is for the period 1 April 2022 to 31 March 2025. It is set within the context of the National Health Service (Scotland) Act 1978 and the Patient Rights Act (Scotland) 2011.

The Provider must notify NSD immediately (or as soon as practically possible and within three working days) if there are any serious concerns including an adverse event, information governance breach or significant non compliance found during audits against local/national standards or protocols.

On notification of a serious concern, NSD will liaise with the Provider and clarify roles and responsibilities. This will include risk assessment, analysis and planning, and coordination of delivery of actions and sharing of any lessons learned.

The Provider should respond to any written requests for reported matters of concern within five days. When NSD or appropriate auditor requests to visit service premises, it is expected that the Provider facilitate this in a timely manner.

2. National Context

NSD acts on behalf of Scottish Government and NHS Boards to plan for and procure national specialist services. NSD supports the National Specialist Services Committee (NSSC). The remit of NSSC is to advise the NHS Board Chief Executives and through them, the Scottish Government Health and Social Care Directorate on designation and provision of specialist services.

NSD has delegated authority from NHS Boards to develop and progress operational changes in service provision in partnership with providing NHS Boards to ensure sustainable delivery of high quality efficient, effective and timely services.

National funding is top-sliced from NHS Boards' allocations and is a limited resource. To ensure this funding is appropriately utilised, reporting standards as outlined in this agreement are a mandatory requirement for all nationally designated specialist services

The Provider will deliver services to meet demand and ensure best possible quality and value from the resources invested in the NHS as outlined in *A National Clinical Strategy for Scotland* (Scottish Government 2016).

The Provider is expected to demonstrate alignment with the *Chief Medical Officer's Realising Realistic Medicine principles.* This includes, putting the patient at the centre of decision making, encouraging a personalised approach to care, reducing harm and waste, tackling unwarranted variation in care, and innovating to improve.

3. Service Specification

3.1 Service overview and objective

The IMD service provides multi-disciplinary, highly specialist care for children and adults with known and suspected Inherited Metabolic Disorders (IMD), including the clinical diagnosis and management of IMD.

Most people with IMD in Scotland are identified due to illness or disability caused by their disorder. They can present at any age, from birth into late adulthood, although most people with IMD will be diagnosed in childhood. Some are identified through the Newborn Screening Programme (which currently screens for 6 IMD) or family genetic screening.

Overall the clinical needs of IMD patients can be separated into three (at times overlapping) categories:

a) Individuals who require life-long specialist medical, dietetic and nursing advice and support to manage their IMD, largely through a strictly controlled diet. This is the largest group of IMD patients, accounting for over half the known Scottish IMD population.
b) People who may benefit from specific 'rarely used' treatments such as enzyme replacement therapy (ERT) and other high cost drugs, high-dose vitamins and co-factors, liver or bone marrow transplants. The rarity of their use requires highly specialist knowledge and experience.
c) People who may suffer metabolic decompensation (crisis) resulting in the need for unscheduled inpatient care. Patients may require access to intensive care and haemofiltration/haemodialysis in order to deal with the critical nature of the situation.

The service is also accessible to other clinicians in Scotland to offer advice on investigations and the clinical management of IMD.

The service is managed as an integrated specialist multi-disciplinary team by NHS Greater Glasgow and Clyde (GGC) and staff are based in Glasgow and Edinburgh.

3.2 Population

The term IMD refers to:

> *a large class of genetic diseases involving disorders of metabolism. The majority are due to defects of single genes that code for enzymes that facilitate conversion of various substances (substrates) into others (products). In most of the disorders, problems arise due to accumulation of substances which are toxic or interfere with normal function, or to the effects of reduced ability to synthesize essential compounds.*[1]

The Society for the Study of Inborn Errors of Metabolism has classified approximately 600 individual IMD.[2] Overall incidence is in the UK is estimated to be less than 1.5 per 10,000 births, but some IMD conditions are extremely rare. Taken together IMD are a significant cause of morbidity and mortality. Individual IMD vary widely in presentation and management depending on the affected body system.

Without early identification and treatment many IMD can lead to severe learning or physical disability and death at an early age.

[1] http://www.bimdg.org.uk/site/index.asp
[2] https://www.ssiem.org/images/centralstore/resources/SSIEMClassificationIEM2011.pdf

There are more than 1300 children and adults known to the Scottish IMD service.

3.3 Scope of service

3.3.1 In Scope

The service covers both adults and children resident in Scotland with a known or suspected IMD. It provides:

- Clinical advice about testing and immediate management in suspected IMD.
- Clinical assessment and diagnosis for IMD.
- Outpatient clinical services for individuals with a confirmed diagnosis of IMD at the two designated centres in Glasgow and Edinburgh, and on an outreach basis in other locations in Scotland.
- Support for the (local) delivery of acute inpatient care for IMD patients[3].
- Access to suitable medicines for all patients who are likely to benefit.
- Day-case support for the initiation of enzyme replacement therapy in Scotland.
- Telephone advice during working hours as well as out-of-hours emergency advice to all Scottish Health Boards.

3.3.2 Out of Scope

The following services and aspects are outside the scope of this agreement:

- Biochemistry and genetics testing
- Paediatric intensive care and critical care
- Adult ITU and HDU
- Inpatient care (bed days and ward support) other than clinical advice to non-IMD specialist healthcare professional who look after inpatients with IMD
- Surgical procedures and other interventions including:
    - haemopoetic stem cell transplants (HSCT)
    - organ transplants, e.g. liver, kidney
    - spinal surgery
    - renal dialysis
- The funding of IMD Risk Share medicines
- The funding of non-SMC recommended medicines including:
    - investigational drugs,
    - medicines available through EAMS schemes
    - homecare costs associated with non-SMC recommended medicines
    - procedures that are part of a research protocol

3.3.3 Exclusion criteria

Adult patients with Heterozygous Familial Hypercholesterolaemia (Heterozygous FH); these patients should be referred to Adult Lipid Clinics.

3.4 Service description / pathway

Any intervention not explicitly detailed below will not be funded as part of the service profile.

3.4.1 Referrals / Entry point to service

The IMD service accepts referrals for patients with a suspected IMD through the following four routes:

[3] This only covers the highly specialist IMD staff time to advise and support the local clinicians who are directly responsible for the inpatients under their care. It excludes the bed days and general ward support for these inpatient stays.

1. Newborn Bloodspot Screening Programme: The national newborn bloodspot screening programme covers six IMDs and has agreed protocols that define onward referral to the children's service for further investigation and treatment of suspected cases of these six IMDs. These protocols will continue to apply, with referrals made by the screening laboratory directly to the IMD service.
2. Metabolic Biochemistry Laboratories – The specialist metabolic biochemistry laboratories in Glasgow and Edinburgh notify the IMD service urgently of any samples that are indicative of a possible IMD. They also alert the local clinician who originally requested the test. The clinical IMD service advises on appropriate investigations and any immediate clinical management required, and will liaise with the clinician who is responsible for the patient.
3. Clinical Genetics Services – Referrals are accepted from clinical genetics of newly diagnosed patients and for discussion of management with families.
4. Children or adults, who present with signs or symptoms that suggest a diagnosis of IMD is highly likely, are accepted following discussion with the consultant paediatricians and adult physicians in the IMD service.

There must be liaison between the Provider and the local referring services to ensure seamless patient transitions.

3.4.2 Initial management

The IMD service:

- Provides immediate care (or advice about immediate care) [4] for patients with acute severe illness resulting from an IMD
- Offers adults and children with a newly confirmed diagnosis of IMD a complete assessment, as per established international and Scottish guidelines
- Ensures that treatment, including high cost medicines such as Enzyme Replacement Therapy (ERT), is offered to all patients who are likely to benefit
- Provides clear written and/or electronic information materials about the specific IMD to the patient and their family

3.4.3 Acute Admissions

The service provides highly specialist staff time to support acute IMD inpatient care in the designated centres in Glasgow and Edinburgh. The bed days and general ward support will be delivered by existing children's and adult services in Scotland and are excluded from the service specification.

A child who is acutely unwell with an IMD will be admitted to a Paediatric Critical Care Unit where they can be managed by the PCC team with advice from the IMD service. Transfer to the Royal Hospital for Children in Glasgow is required in cases where haemodialysis, ECMO or other specialist input not available in Edinburgh, is needed. If a child requires intensive dietary management they may need to be transferred to the Royal Hospital for Children in Glasgow.

Adults who require acute inpatient treatment are admitted to any hospital in Scotland that can provide appropriate care, including access to adult intensive care facilities where necessary. Patients will be managed by local teams with telephone advice from the IMD service.

A robust discharge planning protocol should be in place and regularly audited. This should include established pathways and communication mechanisms with referring clinicians and GPs and other appropriate professionals to ensure safe and effective long-term care of the

[4] Direct care for adults may be provided by a proxy for instance an Intensive Care Consultant.

patient. Communication with GPs must be timely and easily accessible. In particular, arrangements for the prescription of medications must be explicit to ensure clarity and patient safety.

3.4.4 High cost IMD medicines

The service will oversee the prescription of high cost medicines covered by the IMD Risk Sharing Scheme (see Appendix A). The funding for these medicines sits separate from this agreement.

A small number of patients may benefit from non-SMC approved IMD medicines. These products are outside the scope of the risk share and should be funded by individual health boards. The service is best placed to make recommendations about the prescription of these therapies; however, funding approval from the relevant health board of residence has to be sought prior to commencing treatment.

The service will have a Lysosomal Storage Disorder MDT to discuss all new patients who may require ERT (or alternative oral therapies). The MDT will also annually review all patients who currently receive these treatments. This ensures all patients who are receiving high cost therapies are appropriately benefiting. The MDT will highlight patients in whom ongoing treatment should be reviewed and/or stopped.

All prescriptions and homecare provision for medicines funded through the IMD risk sharing scheme are to be managed via the service to enable strategic overview.

3.4.5 Enzyme replacement therapy (ERT)

Initiation of ERT for children is provided on a day-case basis at the Royal Hospital for Children in Glasgow.

Initiation of ERT for adults is provided at the medical day-case unit at the Queen Elizabeth University Hospital in Glasgow. In some cases, it may also be possible to initiate ERT at other appropriate site.

Once patients have been successfully initiated on ERT, arrangements for homecare should be made if this is clinically appropriate.

3.4.6 Ongoing management and follow-up

It is expected that most patients will attend the IMD service for life-long regular follow-up appointments.

The service provides regular outpatient reviews of all patients with a confirmed diagnosis of IMD as per established international and Scottish guidelines and clinical best practice.

Ongoing management also includes:

- Ongoing delivery and monitoring of appropriate approved pharmaceutical and specialist dietary therapies.
- Management of acutely unwell paediatric and adult patients admitted to acute care units across Scotland.
- Referral to other specialised services, e.g. Neurology, Clinical Genetics, Psychology or Palliative Care, as appropriate.
- Implementation of appropriate shared care arrangements.

The service will develop shared care arrangements with local (non-IMD specialist) clinicians to facilitate delivery of care where patients live, but all IMD patients will require regular follow-up and support from the IMD service throughout their lives.

Responsibility for the IMD related clinical care for patients in any shared care arrangement with non-MD specialist clinicians will remain with the service.

3.4.7 Telephone advice

The IMD service provides telephone advice to:

- Patients and carers within the IMD patient cohort Monday to Friday (9am to 5pm) to support their care in-between clinic attendances.
- Clinicians and laboratory staff on the investigation, diagnosis of management of IMD from Monday to Friday (9am to 5pm)

3.4.8 Outreach clinics

Outpatient clinics are provided within the service itself in Glasgow and Edinburgh, and in other locations on an outreach basis. Outreach clinics are provided in:

- Aberdeen
- Dundee
- Kirkcaldy
- Inverness

The national IMD service provides multi-disciplinary medical, nursing and dietetic support to the outreach clinics, with telephone support in between clinics. Local link clinicians (medical, nursing and/or dietetic) should ensure timely and effective communication and local coordination to support shared care arrangements that deliver safe and effective care close to home for patients.

3.5 Interdependencies with other services

The service has formal arrangements with the Newborn Screening Laboratory and the IMD Specialist Laboratories for the biochemical diagnosis and monitoring of IMD patients. Such arrangements will include regular meetings with senior laboratory staff with expertise in IMD.

Consultants in Paediatric Inherited Metabolic Medicine maintain close liaison with Paediatric Anaesthetists, and require access to appropriate Paediatric Intensive Care services at the service's main site.

The service maintains communication links with adult acute and critical care services across Scotland.

Some pregnant women with IMD require assessment and/or management from tertiary maternity care services with experience of managing these conditions in pregnancy. The service must have formalised arrangements with tertiary maternity units via link Obstetricians.

Since many IMDs are multi-system medical syndromes, including cardiac, renal and neurological conditions it is essential that the IMD service has strong clinical links with other specialised services including:

- Blood and Marrow Transplantation Services
- Assessment and Provision of Equipment for People with Complex Physical Disabilities (all ages)
- Spinal Services
- Clinical Genetics Services
- Pre-implantation Genetic Diagnosis Services
- Mental Health Services
- Rheumatology Services

3.6 Activity Levels

The agreed indicative level of annual activity for this service is:

	Adults	Children
Referrals	125	240
New Patients	60	160
Consultant-led OP appointments	810	1010
Dietitian-led OP appointments	270	220
Nurse-led OP appointments	N/A	100
ERT-day ward admissions	15	150
Hospital admissions supported	50	170

NSD in partnership with the Provider will continually review the services' ability to meet indicated levels and consider and agree variations required. This will include any associated changes to the financial profile.

3.7 Performance and Clinical Outcomes

The service will develop and agree with NSD, specific performance and quality measures to give assurance of service quality, effectiveness and performance. impact and health gain. NSD will monitor these measures on an ongoing basis and will reserve the right to request improvement plans where appropriate, and will expect evidence of improvement over an agreed time period.

To facilitate the delivery of the quality ambitions, the six domains of quality offer a framework to measure and assess the service against specific performance and quality measures. The IMD service is expected to report the metric and indicators outlined on the next page:

Six Domains of Quality	Metrics
Performance Measures:	
Equitable: Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location or socio-economic status	• Referrals • Outpatient appointments • ERT day cases • Admissions supported } by NHS Board
Efficient: Avoiding waste, including waste of equipment, supplies, ideas, and energy	• % of DNA for out-patient clinics • % of LSD patients on high-cost medicines with an annual MDT review • % of patients receiving high-cost medicines through homecare
Timely: Reducing waits and sometimes harmful delays for both those who receive care and those who give care	• % of newly identified MCADD NBS newborns seen for a 'face-to-face review' within 24 hours of receiving the screening report • % of newborns with PKU identified by NBS, seen by the IMD team and started on dietary treatment by day 14 of life • % of adult new patients that commence definitive treatment within 3 month of diagnosis
Clinical Outcomes	
Effectiveness: Providing services based on scientific knowledge	• % of patients with urea cycle defects provided with an emergency regimen • % of patients with propionic acidaemia (PA) and methylmalonic aciduria (MMA) (non-Vit B12 responsive) provided with an emergency regimen
Safe: Avoiding injuries to patients from care that is intended to help them	• Evidence of quarterly mortality and morbidity MDT meetings • Number of unplanned hospital admissions related to patients' IMD
Patient focused Outcomes	
Person-Centred: Providing care that is responsive to individual personal preferences, needs and values and assuring that patient values guide all clinical decisions	Engage patients and carers in all aspects of care and provide detail of: • Quality of Life Questionnaires • Patient Reported Experience Measures (PREMS)

The Provider should contribute, where applicable, to national clinical registries. Data from national registries should be incorporated into reportable clinical outcomes and support benchmarking of the IMD service.

4. Regulation, Quality and Performance

4.1 Standards and Guidelines

The Provider must adhere to national and NHS Board policies and procedures to deliver a safe, effective and sustainable service that evidences effective clinical governance. Including:

4.1.1 National Context

- ***The Healthcare Quality Strategy***,(Scottish Government 2010) **which** has been developed to ensure delivery of the highest quality healthcare services.
- ***Health and Social Care Standards***, (Scottish Government 2017) which set out what patients should expect when using health, social care or social work services in Scotland. They seek to provide better outcomes for everyone; to ensure that individuals are treated with respect and dignity and that the basic human rights are upheld.
- ***Duty of Candour*** (2018) as provided in the ***Health (Tobacco, Nicotine etc and Care) (Scotland) Act 2016*** ensuring that every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care causes, or has the potential to cause, harm or distress.
- ***The Patient Rights (Treatment Time Guarantee) (Scotland) Directions*** (Scottish Government 2019) which sets out the arrangements for monitoring and recording the treatment time guarantee and communication with patients.

4.1.2 Service Specific

The British Inherited Metabolic Disease Group (www.bimdg.org.uk) and MetBioNet (www.metbio.net) provide relevant clinical and laboratory guidelines for the service. The European Society for Phenylketonuria and Allied Disorders Treated as Phenylketonuiria (E.S.PKU) produced Guidelines on the treatment and diagnosis of PKU.[5]

Given the rarity of the individual conditions covered by the term IMD, guidelines will not be available to inform all treatment decisions. Patient care delivered by the service is expected to be informed by recognised national and international best clinical practice and Realistic Medicines Principles.

4.2 Safety and Governance

The Provider must operate in a system that functions within a transparent clinical governance framework. The Provider must notify NSD of a designated lead clinician to provide assurance and accountability for the service.

The Provider must comply with ***Healthcare Associated Infection (HAI) Standards***, (Healthcare Improvement Scotland 2015) and Healthcare Environmental Inspectorate requirements which support healthcare associated infection services in monitoring their performance and driving improvement across NHSScotland. Any matters of concern should be reported to NSD.

4.2.1 Risks, Issues and Adverse Events

The Provider must adhere to NHS Board policies and procedures that evidence effective management of risk, issues and adverse events:

Risk and issue management

- The Provider is responsible for mitigating risks, managing issues identified within the nationally designated service. The Provider must comply with the principles of effective risk management.

[5] See: https://www.espku.org/projects/european-guidelines/

- Potential threats to and challenges within systems should be identified at strategic and operational levels. The risks and issues should be entered onto a risk register and control measures should be reviewed at regular intervals.
- The risk and issue register for the service should be referenced in the annual report and any significant risks or issues highlighted. It is expected that the service will detail the mitigation actions in relation to the risks identified and this will be discussed as part of the annual performance review.

Management of adverse events

- The Provider will comply with national guidelines for managing significant adverse events ***Learning from adverse events through reporting and review: A national framework for Scotland,*** (Healthcare Improvement Scotland 2019) to support effective management of adverse events and drive improvements in care across Scotland.
- If a significant adverse event occurs, the Provider should inform NSD with immediate effect (for other adverse events these should be reported within three working days). Thereafter the Provider and NSD will agree the lead investigating organisation, roles and responsibilities of each party.
- The Provider must comply with the principles of Duty of Candour, ensuring transparency with patients, carers and colleagues when an adverse event occurs which causes, or has the potential to cause, harm or distress

4.2.2 Contingency Planning

The Provider must have appropriate contingency plans in the event of any incidents which would impact on delivery of the service. For example, adverse weather, power failure, illness of staff, outbreak of infection, industrial action, failure of essential facilities or specialist equipment.

If an incident occurs, the Provider will assess what essential services must be delivered in line with contingency plans. The Provider must advise NSD of the situation and discuss the contingency requirements.

4.3 Audit and performance outcome monitoring

The Provider will ensure and demonstrate the high quality of the service and constantly seek improvement through systematic clinical audit and use of improvement methodologies.

NHS Scotland's approach to improving the quality of healthcare is set out in the ***Healthcare Quality Strategy for Scotland*** (Scottish Government 2010) and outlines the three quality ambitions for health service across NHSScotland:

- **Safe** - There will be no avoidable injury or harm to people from healthcare, and an appropriate, clean and safe environment will be provided for the delivery of healthcare services at all time
- **Person-Centred** - Mutually beneficial partnerships between patients, their families and those delivering healthcare services which respect individual needs and values and which demonstrates compassion, continuity, clear communication and shared decision-making
- **Effective** - The most appropriate treatments, interventions, support and services will be provided at the right time to everyone who will benefit, and wasteful or harmful variation will be eradicated

NSD will monitor service specific reportable measures as outlined in section 3.7. Additional baseline quality standards, performance targets and indicators established by the Provider should be also be referenced in Annual Report.

4.4 Quality Improvement

The Provider is expected to encourage a culture of audit and continuous improvement. NSD will reserve the right to request improvement plans where appropriate, and will expect evidence of improvement over an agreed time period.

4.5 Person Centred Care

The Provider will deliver a person centred and responsive service, assessing individual needs and consider what would most benefit their health and wellbeing. Patients and their families should be encouraged to take part in decisions about their health and wellbeing and provide them with the information and support to do so as set out in *the* ***Patient Rights (Scotland) Act 2011*** and ***The Patient rights and responsibilities Charter*** (Scottish Government 2019).

The Provider will seek to engage patients and carers in all aspects of care and provide detail of Patient Reported Outcome Measures (PROMS) and Patient Reported Experience Measures (PREMS). It is expected that the service will advise NSD on patient engagement activities, including reporting on surveys, audit and improvements in care directly related to patient and carer feedback.

Treatment specific and general patient information should be available in a written format and/or in a format that takes account of physical, cultural, educational and mental health needs. Person-specific communication should be done verbally by the relevant health care professional. It should, as a minimum, cover the following subject areas:

- the team who will provide their care
- assessment procedures
- treatment options and choices with risks identified
- support and information services available at both local and national level
- practical arrangements – including proposed patient journey, likely length of inpatient stay and discharge and follow up procedures.

4.6 Information Governance

4.6.1 Data protection

The Provider must comply with current Data Protection legislation including the requirements of the ***Data Protection Act (2018)*** and the ***General Data Protection Regulation (GDPR (EU) 2016/679)*** and apply the governing principles outlined in the ***Caldicott Guardians: Principles into Practice*** *(*NHS Scotland 2011*)* for management of personal data. The Provider will, as required:

- Inform NSD of the names and contact details of the NHS Board Caldicott Guardian and Information Governance Lead
- Comply with the ***Data Sharing Code of Practice*** (*Information Commissioner's Office* 2020*)*, including protocols in fair processing of information and reporting serious data breaches to the IGC Office.
- Advise NSD of any serious data breaches, including details of risk and impact on the individual(s)
- Annually audit its information governance practice against the ***Information Sharing Governance Toolkit Scotland*** (Scottish Government 2019)
- Apply guidance on the ***Information Security Policy Framework****, (*Scottish Government 2019) and ***Records Management; NHS Code of Practice****,* (Information Governance Alliance 2016).

The Provider will be the data controller for personal data collected and processed for the purpose of delivering the service. The Provider will ensure that all staff will be trained in safe information handling and aware of their responsibilities in relation to confidentiality.

For quality monitoring and performance management reporting requirements, the Provider should submit anonymised or aggregated data which does not disclose personal patient identifiable information. Only in exceptional circumstances will patient identifiable information be requested by NSD.

4.6.2 Freedom of Information (FOI) and Environmental Information Regulations (EIR)

In line with the Freedom of Information (Scotland) Act 2002 and the Environmental Information (Scotland) Regulations 2004, the Provider should underpin the principles of the Act by encouraging behaviour which is open and transparent and therefore increases public trust.

Where the Provider receives a request for information relating to the service, it will provide NSD with a copy of the response issued if NSD are quoted in the response.

Where NSD receives a request in relation to the service, the Provider will give any assistance required by NSD in forming the response to the request. NSD will ensure that the Provider is given notice of any intended disclosures under FOI or EIR in relation to the service that they provide.

4.7 Complaints

The Provider must publish, maintain and operate a complaints procedure in compliance with the *Scottish Public Services Ombudsman Model Complaints Handling Procedure* (2017).

The Provider must provide clear information to patients, carers and families, and display prominently in the services environment on how to make a complaint.

4.8 Equality

The Provider must comply with the requirements of the Equality Act 2010. The Provider must not discriminate between or against patients on the grounds of age, disability, gender, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sex, sexual orientation, or any other non medical characteristics.

The Provider must provide appropriate assistance and make reasonable adjustments for service users, carers and legal guardians who do not speak, read or write English or who have communication difficulties (including visual, hearing, oral or learning impairments). The Provider must carry out an annual audit of its compliance with this obligation and must demonstrate at the extent to which service improvements have been made as a result.

4.9 Whistleblowing

The provider must comply with the principles of the National Whistleblowing Standards (Independent National Whistleblowing Officer 2021) to ensure an effective procedure is in place, when concerns are raised that meet the definition of a ‘whistleblowing concern’ The Standards must be accessible to those working within the service and a description of the procedure for reporting and handling concerns must be available.

5. Workforce

5.1 Compliance with national employee policy and guidance

The Provider must apply principles of the staff governance guidance outlined in the NHS Scotland Staff Governance Standard (NHS Scotland 2012) and good employment practice detailed in 'Once for Scotland' Workforce Policies.

The Provider has an obligation to ensure:

- applicable staff are registered with appropriate professional bodies and where required, have completed their revalidations
- application of safe pre and post employment checks
- staff are aware and adhere to NHS Board policy in relation to the acceptance of gifts and hospitality

5.2 Staffing

The Provider must demonstrate safe and sustainable staffing levels, which will include:

- skill mix and staffing establishment determined using validated workforce tools, benchmarking and relevant guidance where appropriate
- ensuring that registered and non registered staff are sufficiently qualified and experienced and can access appropriate training when required. Training for staff will be funded by the Provider
- ensuring that services meet national absence target by having effective attendance management processes in place
- All staff must be subject to the local occupational health policy which adheres to best practice.

The Provider must have a programme in place to support absence and maternity leave for staff. The national funding for nationally designated specialist services does not include any provision to cover the cost of additional resources that may be required as a result of sickness, annual leave, maternity leave or any other absence. It is the responsibility of the Provider to ensure that there are adequate staffing levels in place to support the service.

The Provider must nominate and advise NSD of contact details of the lead clinician and responsible senior manager and advise when there are any changes to personnel in respect of these roles.

6. Facilities

The Provider is responsible for ensuring safe and sustainable facilities to support delivery of the nationally designated service and must ensure that there is a planned programme for the maintenance of buildings and associated facilities.

The Provider premises will comply with all relevant legislation and standards outlined by the Health & Safety Executive and Healthcare Improvement Scotland, Healthcare Environment Inspectorate.

The Provider must take all reasonable steps to minimise its adverse impact on the environment in line with the ***Policy on Sustainable Development*** *(NHSScotland 2012)* and demonstrate progress on climate change adaptation, mitigation and sustainable development and influencing and encouraging patients, visitors, staff and suppliers to behave in a sustainable manner.

6.1 Equipment

It is the Provider's responsibility to ensure that an equipment replacement programme is in place to allow the continued delivery of the service. Capital is allocated directly to NHS

Boards but NSD is responsible for funding the revenue consequences of capital purchases. NSD must be consulted when the Provider wishes to invest capital for national services to ensure that NSD can support the revenue consequences of the investment in future years.

7. Research and Development

It is expected that all nationally designated specialist services, facilitate a continuous programme of research, development and quality improvement in line with routine day to day service delivery.

The service should contribute to the Provider's Research and Development workplan and gain benefit from the partnership working between NHSBoards and the Chief Scientists Office to support the infrastructure to allow clinical research, application of best practice and processes that support efficient and effective working

As indicated in section 4.3. The service must continuously demonstrate that they are delivering the service in an evidenced and cost effective manner, by auditing performance and applying best practice to support efficient, effective and innovative working.

8. Reporting and review

The Provider must submit the agreed reports within the specified timescales. Further information may be requested by NSD in relation to the service and it is expected that the Provider will respond to these requests within agreed timescales.

The Provider is responsible for the provision of information to NSD and for the validity, accuracy and timeliness of all returns and data. NSD must not receive in patient identifiable data in any reports which could be subject to public scrutiny.

8.1 Reporting timetable

The Provider will supply the following reports on the progress of the service agreement throughout its duration:

Report	Date due	Format for report
Monthly	10th day of the following month	Annex B
Mid Year report	31 October	Annex B
Nine month finance report	31 January	Annex C
Annual report	31 May	Annex D

Reports should be sent to nss.specialistservices@nhs.scot and not to individual NSD staff).

It is the Provider's responsibility to ensure that all reports are received within the agreed timescales. Failure to submit reports on time will impact on NSD's ability to reconcile funding to expenditure and fulfil the obligation to report to NHS Board Chief Executives on usage and performance of the designated service.

8.2 Annual Performance Review

An annual performance review will be undertaken each year by NSD based upon ongoing discussions and the annual report. The extent of the review meeting will depend on each service's circumstances.

The Provider is expected to work with NSD, when requested, to schedule the annual performance review meeting within an appropriate timeframe and ensure that all required personnel are present.

8.3 Commissioning review process

NSD undertakes reviews of each national designated service on a rolling programme of 3-5 years to ensure that each service is the delivering the most clinically and cost effective service and in line with the original designation objectives. The Provider is expected to participate in all commissioning reviews of the service and support the implementation of review recommendations.

9. Financial arrangements

9.1 Agreement structure & basis of funding

This funded profile takes the form of a cost and volume agreement under which the Provider will be entitled to receive an agreed sum reflecting the actual fixed costs of the service, together with an amount to cover the actual variable costs incurred in the delivery of activity by the service.

Funding for the first quarter of the financial year will be transferred during the June month end, with subsequent transfers completed on a monthly basis.

Initially, revenue transfer values will be calculated on the basis of the indicative budget that has been agreed and detailed in this Agreement. However, on receipt of the 6 month and 9 month finance reports, and as long as variations in activity and cost are within 10% of indicative values, funding transfers will be adjusted to bring funding in line with year to date actual costs and full year expenditure forecasts.

The Provider's finance team will be contacted in early April to agree outstanding balances and funding mechanisms will be put in place to ensure that the final funding level for the year matches the actual costs incurred by the service.

Should it become apparent, at any point during the year, that activity and/or costs are likely to differ significantly from the indicative levels set out in this agreement (for the purpose of this agreement, material variations in activity and expenditure will be assumed to be +/-10%) then the onus is on the service to contact NSD and initiate negotiations around activity and funding, for both the current year, and for future years (if it is felt that any material variations are likely to be long term).

9.2 Funded value of agreement

[redacted]

A full breakdown of the funded value is available in Annex E.

9.3 Cost shifting & Cross Subsidisation

The Provider shall not take action to shift activity or costs to other budgets or to make agreements with other commissioners or providers without prior consent in writing from NSD.

9.4 Capital funding

It is the Provider's responsibility to ensure that a capital and equipment replacement programme is in place to ensure the continued delivery of the service. Capital is allocated directly to NHS Boards but NSD is responsible for funding the revenue consequences of capital equipment purchases. NSD must be consulted when the Provider wishes to invest capital for national services to ensure that NSD can support the revenue consequences of the investment in future years.

NSD receives a nominal capital allocation to augment the capital replacement programme put in place by the Provider. This allocation is to ensure that any dated or failing equipment can be replaced before service delivery is compromised. The allocation does not cover buildings or infrastructure. The Provider will therefore ensure that the service has a planned programme for the maintenance of the buildings and facilities.

The Provider will be invited to submit applications for capital investment by June of each year. Applications must be submitted by the Provider's management team. NSD will undertake a prioritisation process and will allocate the capital funds to Providers where there is risk to delivery of the service. Procurement must be completed before the end of the financial year.

Minor capital (items under £5,000 including VAT) is funded by revenue. All minor capital purchases not explicitly included in the indicative baseline should be requested in a business case to NSD.

9.5 Charging for other UK residents

Assuming that there is no diminution in the service made available to Scottish residents, UK residents may be treated under this agreement. Their activity should be allocated against this agreement and a sum equivalent to the value of that income will be removed from the baseline funding provided by NSD.

The provider will ensure that all non-Scottish residents are charged for at full cost-per-case rates, including fixed costs.

9.6 International patients

Treatment of international residents through reciprocal health arrangements is the responsibility of the host NHS Board and, as such, is excluded from the baseline of all national agreements. [Note: this includes the Republic of Ireland and the Isle of Man, for whom the Provider must make funding available.]

Anyone not covered by reciprocal health care agreements is considered a private patient and must be able to provide proof of funding (either personal or from their own health system) before any referrals can be accepted. Again, these patients should be treated within the national service and the costs of their care reflected as income against the NSD-funded baseline.

10. Changes to terms of the agreement

10.1 Changes to service specification

Significant changes as to how the service is delivered (for example which treatments are offered or conditions treated) will be only made following the submission of a business case to NSD and approval by NSSC. There must be formal written agreement between NSD and the Provider before changes are implemented.

Other significant changes to the service may result as a recommendation from a major review. These changes will only be applied following approval by NSSC and written agreement between NSD and the Provider on a plan for implementation.

10.2 Notification times

Changes to the terms of the agreement will only be made following formal written agreement between NSD and the Provider unless there are exceptional reasons for deviating from this procedure. Minimum notification times are:

- Six months' notice of any proposed changes in the agreement which require a reduction in staffing
- Two months' notice of any other material changes by either NSD and/or the Provider

Changes to the terms of the agreement will be considered in the event of unforeseen circumstances such as:

- The occurrence of major incident
- Emergency needs
- A major outbreak of illness or infection
- Industrial action

10.3 Sub-contracting

No sub-contracting shall be undertaken without the prior agreement in writing from NSD.

11. Resolution of disputes

NSD and the Provider both resolve wherever possible to settle any disputes or disagreements in relation to this service agreement by negotiation.

When a resolution cannot be reached, this will be escalated to the relevant group or committee to resolve eg National Specialist Services Committee, Scottish Government, Scottish Association of Medical Directors as appropriate.

12. Distribution

A copy of this service agreement is to be held by the provider.

For and on behalf of the Scottish Government

Signature [redacted]

Block Capitals SUSAN BUCHANAN

Designation DIRECTOR
National Services Division

Date- 02/06/2022

For and on behalf of NHS Greater Glasgow & Clyde

Signature [redacted]

Block Capitals MELANIE HUTTON

Designation GENERAL MANAGER
NHS Greater Glasgow & Clyde

Date 03/02/2023

Signature .....

Block Capitals .....
Clinical Lead

Date .....

Annex A

IMD Risk Shared Medicines

The medicines listed below are only included in the risk share for the specific indications listed and only in the specific circumstances described within the reimbursement criteria section of this document.

- Medicines included in the risk share arrangements prior to establishment of Scottish Medicines Consortium (SMC):
  - Agalsidase alpha (Replagal) for the treatment of Fabry Disease
  - Agalsidase beta (Fabrase/Fabrazyme) for the treatment of FabryDisease
  - Imiglucerase (Cerezyme) for the treatment of Type 1 Gaucher Disease

- Medicines accepted for use by SMC:
  - Miglustat (Zavesca/Vevesca) for the treatment of Type 1 Gaucher Disease.
  - Velaglucerase (Vpriv) for the treatment of Type 1 Gaucher Disease.
  - Migalastat (Galafold) is indicated for the long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation (from 7 November 2016 as part of a Patient Access Scheme).
  - Eliglustat (Cerdelga) for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 poor metabolisers, intermediate metabolisers or extensive metabolisers (from 11 December 2017 as part of a Patient Access Scheme).
  - Volanesorsen sodium (Waylivra) for genetically confirmed familial chylomicronaemia syndrome (FCS) and at high risk for pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate (approved approved via SMC ultra-orphan pathway in November 2020).

- Medicines accepted for restricted use by SMC:
  - Carbaglu (N-carbamoyl-L-glutamic acid) for the treatment of hyperammonaemia due to N-acetylglutamate synthase deficiency.

- Medicines not recommended by SMC but included in the risk share if there has been a recommendation following Individual Patient Treatment Request (IPTR)/Peer Approved Clinical System (PACS) within the NHS Board of residence of the patient:
  - Alglucosidase alfa (Myozyme) for the treatment of Pompe disease (acid maltase deficiency).
  - Laronidase (Aldurazyme) for the treatment of MPS 1, Hurler-Scheie or Scheie syndrome.
  - Idursulfase (Elaprase) for the treatment of MPS II (Hunters syndrome).

New high cost IMD medicines are added automatically to the scheme if they are approved through the ultra-orphan pathway.[6]

[6] https://www.scottishmedicines.org.uk/how-we-decide/ultra-orphan-medicines-for-extremely-rare-conditions/

Excluded medicines

The following orphan drug therapies are not recommended by the SMC for these indications, therefore are **excluded** from the risk share arrangements:

- Miglustat (Zavesca/Vevesca) for the treatment of progressive neurological manifestations in adult patients and paediatric patients with Niemann-Pick type C disease.
- Kuvan (Sapropterin) for the treatment of PKU.
- Elosulfrase alpha (Vimizim) for the treatment of mucopolysaccharidosis, type IVA (Morquio A Syndrome, MPS IVA) in patients of all ages.

The following therapy was proposed for inclusion in the risk share but as it has not yet been considered by the SMC, it is therefore **excluded** from the risk share arrangements:

- Galsulfase (Naglazyme) for the treatment of MPS VI (Maroteaux-Lamy syndrome).

Reimbursement criteria

New registrations are only accepted from the Scottish Inherited Metabolic Disorders Service. Prescription arrangements for patients who are already covered by the scheme are not affected.[7]

[7] It is envisaged that these prescriptions will be migrated to the Scottish Inherited Metabolic Disorders Service over the next 2 years. Details of this process still have to be worked out. The IMD service will contact prescribers.

Service Agreement – IMD Service

Annex B

Provider: NHS Greater Glasgow & Clyde

Service: Inherited Metabolic Diseases

Report format: Monthly reporting and six month report

Monthly reporting template

Service Activity	Jan		Feb		etc.		Total	
	Paed	Adult	Paed	Adult	Paed	Adult	Paed	Adult
Referrals								
New patients								
Consultant-led OP appointments								
Consultant-led adult outpatient appointments								
Dietitian-led OP appointments								
Nurse-led OP appointments								
ERT day-ward admissions								

Six month report

1. Report of Actual V Planned Activity:
Information on referrals, assessments and admissions for treatment must be broken down by NHS Board of residence.

2. Notification of anticipated problems.
Identify any issues in relation to any of the following areas which may be impacting on the performance of the service:

Resources, Workforce, Waiting/Response Times, Audits, Performance & Clinical Outcomes, Risks & Clinical Governance issues, Adverse Events, etc.

3. Potential developments in future years with financial implications.
Service to indicate developments with potential financial implications for future years.

4. Financial report (as below):

This section should detail expenditure to date against funded value and explain any significant variances from planned including yearend financial outturn.

	Agreement value to 30 September	***Actual expenditure to 30 September***	***Projected outturn to 31 March***
Costs as per Annex E			
Total			

Service Agreement – IMD Service

Annex C

Provider: NHS Greater Glasgow & Clyde

Service: Inherited Metabolic Disorders (all ages)

Report format: Nine month report

Financial projections

	Agreement value to 31 December	***Actual expenditure to 31 December***	***Projected outturn to 31 March***
Costs as per Annex D			
Total			

Comment on any material variances from planned expenditure

Forward year baseline

	Current NSD funded value	***Proposed baseline***	***Variance***
Costs as per Annex D			
Total			

All variances must be fully explained.

Developments not previously agreed with NSD must be supported by a full business case.

NB *Developments highlighted at this late stage will not normally be considered for funding from 1 April of the following year*

Service Agreement – IMD Service

Annex D

Provider: NHS Greater Glasgow & Clyde

Service: Inherited Metabolic Disorder (all ages)

Report format: Annual report

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1. Service Delivery
- 1.1 Overview of service
- 1.2 Service Description

2. Activity Levels

3. Performance and Clinical Outcomes
- 3.1 Equitable
- 3.2 Efficient
- 3.3 Timely
- 3.4 Effectiveness
- 3.5 Safe
- 3.6 Person centred

4. Quality and service Improvement

5. Governance and Regulation
- 5.1 Clinical Governance
- 5.2 Risks and Issues
- 5.3 Adverse Events
- 5.4 Complaints and Compliments
- 5.5 Equality

6. Financial reporting and workforce

7. Audit & Clinical Research / publications

8. Looking ahead

Service Agreement – IMD Service

Annex E

Provider: NHS Greater Glasgow & Clyde

Service: Inherited Metabolic Disorders (all ages)

Report format: Financial Reporting