Service Specification No.	1.
Service	Community Macular Service
Commissioner Lead	
Provider Lead	
Period	01/04/22 – 31/03/23
Date of Review	

1. Population Needs

1.1 National context and evidence base

The incidence and burden of eye disease is increasing steadily as the population ages. Many eye diseases are chronic meaning patients must be managed over the long term. The eye diseases in the UK with the greatest incidence and highest care costs are cataract, chronic open angle glaucoma, age-related macular degeneration (AMD), and diabetic retinopathy.

Fight for Sight (www.fightforsight.org.uk), the eye research charity highlights the prevalence of eye conditions:

- Every day 100 people in the UK start to lose their sight;
- Almost 2 million people in the UK are living with significant sight loss, predicted to rise to around 2.3 million by 2020 and almost 4 million by 2050;
- Around 360,000 people in the UK are registered blind or partially sighted
- An estimated 25,000 children in Britain are blind or partially sighted; and
- 86% of people in the UK value sight above any other sense

In 2008 by the leading eye health and sight loss organisation across the UK developed the *UK Vision Strategy* to enable them to deliver a united approach to delivering change. The Strategy is the UKs response to the World Health Organisation (WHO) Global Action Plan for the Prevention of Avoidable Blindness (formerly the VCISION 2020 Action Plan). The UK Strategy was refreshed in 2013.

The Strategy aims to transform the eye health of the UK and enable those with sight loss to receive timely treatment and support so they can live independent lives. The updated strategy (2013 – 2018) seeks to achieve three outcomes (www.ukvisionstrategy.org.uk) :

- Everyone in the UK looks after their eyes and sight;
- Everyone with an eye condition receives timely treatment and, if permanent sight loss occurs, early and appropriate support; and
- A society in which people with sight loss can fully participate

With the rising prevalence, hospital eye attendances are increasing rapidly with over 10 million outpatient appointments in England alone in 2013/14, up from 5.5 million in 2008/9 (www.rcophth.ac.uk). This increase is largely due to the ageing population but also because previously untreatable conditions have become treatable, transforming the outlook for people who would have inevitably have gone blind in the past. Wet-AMD, DMO and RVO are prime examples. HES' have failed to keep up with many becoming overloaded. As a result the DH, Royal College of Ophthalmologists (RCOphth) and College of Optometrists have worked together to modernise care within HES' and to provide guidance to enable more care to be delivered in the community. This includes an enhanced role for community and non-medical practitioners.

1.2 Clinical Context

Age related Macular Degeneration (AMD) is the commonest cause of blindness in older people in the developed world. Most suffer from Dry AMD which causes a relatively slow deterioration in central vision and for which there is currently no effective treatment. 10 – 15% of Dry AMD patients progress to Wet AMD with an estimated 26,000 new cases per annum nationally. Approximately 70% of patients are affected in both eyes.

Wet AMD became treatable in 2008 with the licensing of Anti-VEGF (anti-vascular endothelial growth factor) therapies. Treatment entails multiple injections for most patients often for many years and so the demand on macular services is increasing exponentially. Anti-VEGF treatments are far superior to photo-dynamic therapy (PDT) which is destructive to the retina and is recommended for just one particular form of Wet AMD.

In 2013, Anti-VEGF was licensed for two further indications. Diabetic Macular Oedema (DMO) and Retinal Vein Occlusion (RVO) adding approximately 50% to those eligible for treatment. Subsequently HES' are finding it increasingly difficult to manage demand.

Radiotherapy (Oraya Therapy) has recently joined the treatment options for Wet AMD. This treatment delivers a focussed beam of low dose radiotherapy onto the affected part of the macular. It is non-invasive and targets the diseased area at the back of the eye to inhibit further growth of abnormal blood vessels which cause AMD to be wet/active. The treatment is a simple outpatient procedure with no limitations on patient activities after treatment. It needs to be given in combination with anti-VEGF injections and is likely to become standard practice within the next year or two.

- www.dh.gov.uk/health/2012/08/programme-budgeting-data/
- www.ukvisionstrategy.org.uk
- www.hesonline.nhs.uk/ease/contentserver?siteid="1937&categoryID=895"
- www.commissioningforeyecare.org.uk

1.3 Local context and evidence base

Currently the local Secondary Care providers do not offer macular treatments and consequently Greater Preston and Chorley and South Ribble patients travel to surrounding Trusts for treatment. This is inconvenient at the very least for people who are often older with failing vision and, we suspect leads to poorer clinical outcomes secondary to a higher drop-out rate.

NHS Greater Preston CCG and Chorley & South Ribble CCG (the CCG's) wish to procure an integrated community macular service to meet the needs of its population. The new service will manage all new cases of Wet Age Related Macular Degeneration (Wet AMD), Diabetic Macular Oedema (DMO) and Retinal Vein Occlusion (RVO) and any other retinal conditions that become recognised as treatable by NICE over the life of the contract. Once established, the provider will open the Service up to existing patients and facilitate transfer for those who choose to do so.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	
Domain 2	**Enhancing quality of life for people with long-term conditions**	**X**
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	
Domain 4	**Ensuring people have a positive experience of care**	**X**

Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**X**

2.2 Local defined outcomes

The Macular Service will be expected to deliver the following outcomes:

- A single integrated consultant led service managing all new patients with treatable macular conditions - and repatriating existing patients who so wish once the service is established
- The CCGs can be assured that GPCSR patients are achieving the best possible clinical outcomes by receiving the right treatment at the right time
- Open and transparent performance monitoring shared with commissioners
- A culture of partnership with the CCGs to steadily develop and improve this service over time to include gain / risk share
- Support the development of a resilient and sustainable specialist workforce by being approved for higher specialist training by Royal College of Ophthalmologists, specialty optometrist training and specialist Ophthalmic Nurse training
- A culture of Continuing Quality Improvement informed by a comprehensive audit programme.
- Best value for money

2.3 Whole System Relationships

2.3.1 Interdependencies

Patients will be wholly managed by the Service although it is essential that the service integrates with the wider health economy.

Key interdependencies include:

- Local community optometrists and the Local Optical Committee
- Local GPs
- Psychological and mental health services
- Low Vision Aids provision
- Social care and third to support those for who suffer visual impairment
- Referral Management Centre

2.4 Equality

The CCGs are committed to preventing discrimination, valuing diversity and achieving equality of opportunity. The availability of care and quality of service must be based on individual clinical need and should be equally available to all regardless of:

- Gender
- Age
- Race
- Religion
- Sexual orientation
- Disability
- Marital status
- Gender reassignment
- Pregnancy and maternity

Keeping the above list of protected characteristics in mind, the Service will ensure:

- The privacy and dignity of patients by ensuring informed consent for treatment and access to a chaperone is available;
- A convenient service availability (see 4.5) to include students and those who work full time;

- Patient information to preferably display the Information Standard Certification and be available in the range of languages spoken in GPCSR.
- Disabled people are able to receive care in the Service without impediment

The Provider will establish a mechanism to ensure there are clear feedback mechanisms for patients and stakeholders and that such feedback is representative of the cohort of the patients it sees. It will link with the CCGs' Communications & Engagement Teams and ensure that the Service is promoted through NHS Choices and a wide range of minority groups' publications / websites.

3. Scope

3.1 Aims and Outcomes

The provider will deliver a service with the following outcomes:

3.1.1 Clinical Outcomes

Top decile clinical outcomes for macular patients by delivering:

- 100% of new patients to have their first injection within 14 days of referral
    - 90% within three days and >50% on the next working day
- All subsequent injections given in accordance with a personal care plan which in turn is based on current best "treatment to plan" guidance
- A macular register of all patients
- Top decile improvements in both visual acuity and contrast sensitivity measured regularly
- Patient quality of life, anxiety and depression scores measured regularly, which demonstrate steady improvements over time
- Top decile ocular infection rates other major complications
- Clinical practice in line with NICE, Royal College of Ophthalmology and College of Optometrist and other relevant guidelines
- Equity of clinical outcomes across all clinical groups
    - NOTE, this is not the same as equity of provision
- No patients who meet the "cease to treat" criteria as defined by the RCOphth or who choose to cease treatment will continue to have treatment
- No patient drops out of treatment without a fully informed decision having been made by the patient in discussion with a clinician
- Full support and smooth transfer of care those with deteriorating vision or blindness
    - Mental health, social care, low visual aids services and third sector providers

3.1.2 Patient Experience

- The best possible patient experience by providing:
    - A convenient local service
    - Minimal time spent in the department at each visit
        - 30 minutes for diagnostics / consultation only
        - 60 minutes where the patient also receives an injection
    - Patient education and shared decision making so that everyone feels fully informed about their condition and treatment options
        - Patients always know they have the option to cease treatment should they wish
    - A positive patient experience in a welcoming and friendly environment
    - High levels of patient satisfaction with >90% people recommending the service to family and friends
    - Levels of service ensuring low drop-out and DNA rates and increased patient

compliance

3.1.3 Value for Money

- Excellent value for money through:
  - A low but sustainable local tariff
  - Wholehearted adoption of "Avastin through Choice" as soon as legislative and regulatory circumstances permit
  - Adopting new technologies and treatment regimens as they emerge to streamline care and reduce the need for injections e.g. Oraya Therapy,
  - A leading edge approach to service models and skill mix.

The CCGs expects a service that not only achieves the above outcomes but also routinely and reliably demonstrates that they are being achieved.

3.2 Referrals, secure pathways and access

The Macular Services would provide patients with consultant led clinical assessment, diagnostic and treatment services for patients presenting with the following conditions:

- Wet AMD;
- Diabetic Macular Oedema (DMO); and
- Retinal Vein Occlusion (RVO)
- Other conditions that become treatable as determined by NICE guidance

The timing of the first injection is critical, particularly for Wet AMD patients with some reporting daily deterioration of their vision whilst waiting for treatment. The provider will put processes in place to ensure new patients are seen AND receive their first injection within the Royal College Guidance of 14 days with the majority of patients much sooner than this; 90% within 3 working days and >50% on the next working day. This may include telephone booking of booking by fax and initial referrals do not need to go via the RMC (although they should be informed when a referral has been made). Whatever process is put in place must include fail safe measures to ensure completion.

The principal reason for requiring the provider to achieve rapid assessment and diagnosis is to enable the first injection to be given as early as possible. It is also to give those few patients who are unsure whether they want to embark on a regime of intraocular injection the time to reflect and still come in within Royal College guidelines ("pause for thought"). The provider should have processes in place to support patients and carers to make a fully informed decision. No-one is to receive their first injection beyond 14 days unless it is the patient's express wish to delay or not be treated.

Macular clinics will be led by a Medical Retinal Specialist Consultant ophthalmologist, either on-site or remotely, with the support of ophthalmic specialist nurses, specialist optometrists and ophthalmic retinal photographers / technicians. If any part of the pathway is undertaken by an ophthalmic specialist nurse/optometrist, that clinician must have ready access to consultant support. Any delegation to non-medical clinicians must be in line with the RCOphth guidance (2013). Further delegation must meet the GMC delegation and referral guidance and prescribing guidance.

Should Oraya Therapy (OT) become commissioned all patients should be assessed for their suitability for OT on diagnosis and OT should, with fully informed consent, be delivered prior to the second loading dose in all suitable patients that choose this option.

Patients drop out of treatment for many reasons although detailed evidence is lacking on precisely why. It is the commissioners' view that people should cease treatment if they so choose or if the treatment is no longer effective but that that is an informed decision between clinician and provider every time. Simple default is not acceptable. The provider will have processes in place to ensure that they know the status of every patient and that patients who default are followed up until such time as a fully informed joint decision has been made and recorded on the macular register.

Deteriorating vision can have significant impact on people's quality of life and mental health with depression common. The provider will routinely monitor people mental health and well –being as well as their ability to cope with daily living and should provide support / signpost to other services where appropriate. This should particularly be the case as they approach the end of their treatment. Commissioners require a thoroughly effective programme to be in place for all such patients.

3.5 Patient and Carer education

Active macular disease is a life changing and frightening diagnosis and patients need to be fully informed of the reality, their likely progress over time and their options around treatment. All patients and their carers should be offered an education programme tailored to their needs to include face to face sessions and on-line or printed material in a format they can access including large font and in the relevant language. Education should be a standing feature of all consultations thereafter.The provider must access local healthy living networks and literature where possible.

The CCGs wish to see a robust approach to Shared Decision Making with patients. We believe some patients continue to be treated when they no longer want to be or are gaining no real benefit. We expect every care plan to include a 6 monthly "pause for thought" in which patients have the time, the information and the support they need to make a reasoned decision on whether to proceed. This does not imply that treatment will pause, merely that patients will be formally reminded they have a choice. Those deciding to stop should be offered direct access back into the service should they change their mind.

3.6 Patient experience

The provider will be expected to undertake integral patient experience programmes to gather, analyse, understand and measure patient experience. Patient experience work should be achievable and align with anticipated outcomes and benefits from a new/redesigned service.

The aim of the programmes will be to secure qualitative and quantitative intelligence to inform demonstrable improvement in patient/user and carer/representative experience. The expectations placed on any existing provider build on and are additional to existing programmes of patient experience work to ensure measurement of the impact of any new service in respect of patient experience, utilising where possible baseline data. Patient experience is a key placeholder in determining if a service is effective. The provider should correlate patient and carer/representative experience with health outcomes and staff experience data.

The focus of patient experience work will be around overall satisfaction, outcomes and quality of life and the aim will be to ask questions about (but not limited to):

- Overall experience
- Dignity and respect
- How involved the person/their representative/carer felt in their (the patient's) care

3.6.1 Patient Experience baseline data

Gathering of intelligence to assess baseline data around patient experience is imperative to be able to measure the success in terms of maintained and/or improved patient experience of any new service. Where no baseline data is available there will need to be a first contact survey to gather baseline data as any new service is implemented. This will help to understand if any new service demonstrates an improvement in comparison to any equivalent service previously provided.

3.6.2 Complaints

The provider will be expected, as part of the patient experience agenda, to have in place appropriate capacity and capability to manage complaints in accordance with current complaints legislation and in any associated contract (complaints includes where a provider is an NHS body Patient Advice and Liaison - for none NHS bodies such equivalent service). This includes concerns and enquires raised by or on behalf of patients and their families. Specific requirements placed on

a provider will be detailed in this specification. Intelligence in the system in respect of complaints from service users and their representatives will be utilised to allow comparative analysis of any complaints received in respect of a redesigned service and/or by any new provider of an equivalent or similar service.

3.7 Population covered

The service will be provided for all resident and registered patients with a GP practice within the geographical footprint of Chorley & South Ribble CCG and NHS Greater Preston CCG. For further information, please visit:

- www.greaterprestonccg.nhs.uk
- www.chorleysouthribbleccg.nhs.uk

3.7.1 Any acceptance and exclusion criteria and thresholds

Ant patient registered with a GPCSR GP in whom treatable macular disease is a possibility.

The CCG also support Anti-VEGF for patients with vision better than 6/12 if:

- There is active disease as demonstrated by OCT
- There is reducing visual acuity or increasing distortion due to Wet AMD and
- The risks have been explained to the patient.

3.7.2 Exclusion Criteria

- Exclude under the age of 18 years old
- Any patient who does not fit the latest National criteria for treatment i.e. the NICE criteria for anti-VEGF therapy excluding the inclusion point above.

4. Supporting Considerations and Services

4.1 Workforce

The Commissioners are seeking a single integrated high quality service Macular Service. Clinical workforce for such a service could include but is not limited to the following:

- Community Optometrists;
- GPs with special interest in Ophthalmology (GPwSI);
- Consultant Ophthalmologists;
- Associate Specialists in ophthalmology;
- Ophthalmic Medical Practitioner;
- Orthoptists; and
- Ophthalmic Nurses

4.1.1 Workforce standards

Notwithstanding main contract clause GC5, the main resource of any provider is a workforce made up of a mix of clinical professionals (as indicated above) committed to providing safe, effective care to all patients, at all times and in all situations.

The Provider will enable the workforce to deliver on this commitment, now and into the future, by promoting and providing high quality relevant education and training for every member of the workforce individually and in teams.

In order to fulfil its obligation to deliver the service the Provider will undertake appropriate workforce planning activities to ensure its capacity and demand modelling will deliver the required activity.

4.1.2 Qualifications and Mandatory Training

All staff must be appointed in line with professional qualifications / standards as appropriate and continue to update skills in line with professional codes of conduct. The Provider must maintain a record of the dates and training given to all clinicians and staff working within the service. All such records should be immediately available to the Commissioner for audit purposes on request. The Provider must ensure that training requirements and competencies are monitored through regular assessment and staff appraisal and that staff are enabled to progress through supported learning

No healthcare professional shall perform any clinical service unless he / she have such clinical experience and training as are necessary to enable him / her properly to perform such services. The Provider shall be responsible for ensuring that their staff:

- Have relevant professional registration and enhanced checks undertaken prior to seeing patients alone;
- Have, prior to starting in post, provided two references (clinical if applicable), relating to two recent posts (which may include any current post) as a health care professional which lasted for three months without a significant break, or where this is not possible a full explanation and alternative referees;
- All access robust induction training applicable to their individual role;
- Have access to and evidence of safeguarding training and development in line with their professional bodies recommendations; and
- Undertake annual audit to ensure compliance with the above.

4.1.3 Workforce requirements

The Provider must have in place a comprehensive, coherent, robust plan for recruitment, management and development of staff with the principle objectives to:

- Meet the essential day to day staff leadership, management and supervisory needs to the contract during its lifetime, including during mobilisation and, if appropriate, contract termination;
- Adhere to TUPE legislation (as applicable);
- Support the provision of safe, high quality clinical services;
- Ensure through appropriate audit, training and continuous professional development that all staff involved in treating NHS patients are and remain qualified and competent to do so;
- Support the implementation of all relevant statutory and non-statutory NHS standards, regulations, guidelines and codes of practice;
- Maintain an effective working partnership with local NHS employers to continuously develop and maintain best people management practices and ways of working; and
- Reduce dependency on agency or locum staff to delivery services, such use not to exceed 10% unless in extreme circumstances.

The Provider must have in place a recruitment and retention strategy. This must:

- Be capable of attracting and retaining high quality job applicants;
- Optimise individual skill levels and potential;
- Fully harness available skills and commitment; and
- Encourage and engender support for new ways of working.

There are continual challenges to the UK's viability to opt out of the Working Time Directive on a European basis and therefore to sustain the future viability of this service the Provider must have in place a working hour's policy which ensures the health and wellbeing of staff and users of the service. This policy must also cover the working hours of clinical staff outside of the service, and in particular, the Provider must ensure they have a mechanism in place which supports them in

reviewing and monitoring the hours worked by clinical staff and assuring themselves that the service they provide is safe. The Provider must have in place a staffing strategy to meet specified levels of service that identifies the requirements for support ancillary staff services. The strategy should include contingency plans for times of high demand and/or high levels of staff absence. The Provider must have in place mechanisms for keeping the commissioner informed when staffing capacity is unlikely to meet demand and the actions that will be taken to address this. It is expected that the Provider will have in place mechanisms to actively review and monitor the working hours of all staff members. The Commissioners reserve the right to carry out unannounced audits to assess compliance.

4.1.4 Workforce standards

The Provider must ensure that all proposed workforce strategies, policies, processes and practices comply with all relevant employment legislation applicable in the UK.

In addition the Provider is required to comply with the provisions of the following policies and guidance as amended from time to time:

- NHS Employment Check Standards, March 2008 (revised July 2010);
- Registration with Care Quality Commission (http://www.cqc.org.uk/);
- Criminal Records Bureau Code of Practice and Explanatory Guide for Registered Persons and other recipients of Disclosure Information published by the Home Office under the Police Act 1997 (revised April 2009) ("Code of Practice on Disclosure");
- The DH's guidance on the employment or engagement of bank staff, if any;
- Any guidance and/or checks required by the Independent Safeguarding Authority or any other checks which are to be undertaken in accordance with current and future national guidelines and policies;
- All guidance issued by the Care Quality Commission including the guidance entitled "Compliance: Essential Standards of Quality and Safety (March 2010)" and any other guidance issued by the Care Quality Commission from time to time;
- The Code of Practice for the International Recruitment of Healthcare Professionals (December 2004) www.dh.gov.uk/assetRoot/04/09/77/34/04097734.pdf ;
- The Cabinet Office Statement entitled "Principles of Good Employment Practice (December 2010);"
- The Cabinet Office Statement; and
- All relevant employment legislation and codes of practice applicable in the UK.

The Provider has the following responsibilities in line with the delivery of this service:

- Initial Training and Accreditation for clinicians, such as Optometrists or GPwSI, including protocols and conditions to be obtained by the Provider and to be signed off by the Commissioners;
- To ensure that all members of the service maintain their knowledge and skills by keeping up to date with the ophthalmic literature, attending meetings and participation in in-house academic sessions. This requirement would be assessed during an annual appraisal;
- To provide clinical education to practices within the locality to support further development of their knowledge and skills in the on-going management of patients; and
- To ensure that all professional staff are supported to undertake clinical supervision in line with the relevant statutory body requirements

4.2 Equipment

It is the responsibility of the provider to purchase, maintain to a high standard and replace all relevant equipment required to provide the service. The CCGs will expect a detailed plan for both the commissioning and maintenance of all equipment and clear accountability for making sure its implementation

4.3 IM&T

The Provider must ensure that appropriate "IM&T Systems" are in place to support the service. "IM&T Systems" means all computer hardware, software, networking, training, support and maintenance necessary to support and ensure effective delivery of the services, management of patient care and contract management.

Clinical details will be recorded on an electronic record from the outset. The IT system will automatically collect a Minimum Dataset from each record, collates them from across the service and presents them to the provider as a clinical dashboard. The CCGs will have open access to an anonymised version. It will also send a short summary to the patients' GP in a format to be agreed with the LMC.

The IM&T solution must enable:

- Individual electronic patient health records;
- Inter-communication or integration between clinical and administrative systems for use of patient demographics;
- Clinical services including ordering and receipt of diagnostic procedure results and reports, where appropriate;
- Prescribing and dispensing where appropriate;
- Access to knowledge bases for healthcare at the point of patient contact; and
- Access to research papers, reviews, guidelines and protocols

4.4 Medicines Management

CCGs will only pay for commissioned High Cost Drugs (HCDs) that are PbR excluded and are used for the indications and within the criteria stipulated in accordance with the following:

- Positive NICE TAs or
- A locally agreed policy/pathways e.g. GMMMG or
- Part of agreed innovation payments or
- Part of excluded services

CCGs will not fund any use of a HCD that is not covered by the above (and only so long as the patient meets the inclusion criteria & continuation criteria for use). Any use of an excluded medicine outside of these specific groups will be the financial responsibility of the provider.

There are currently two main anti-VEGF injections both of which have their pros and cons. Others are in the pipeline and are likely to be approved by NICE within the life of the contract. The commissioners believe that the choice of agent is principally a clinical one, especially as the differences in annual costs are small. However, this may not always be the case and the provider must be willing to adapt practice should price differences become important.

Avastin (Bevacizumab) is an Anti-VEGF agent that is roughly 10% of the cost of the other two agents and the RCOphth, WHO and others recommend its routine use in treatable macular disease. It is not, however, licensed in the UK. The provider must be prepared to enthusiastically embrace Avastin through Choice at such time as the legislative and regulatory environment allows.

4.4.1 Drugs Data Provision

To facilitate auditing by commissioners to confirm that patients are being treated in line with NICE or locally agreed policies for HCDs, the provider will be required to submit a Minimum Data Set (MDS) of information in an approved format which includes:

- Medicines name
- Form and strength
- Dose given
- Date given
- Cost to the provider

- The indication for which the medicine was given
- NHS number (which will be pseudo-anonymised by DSCRO) to allow commissioners to cross reference with invoice information e.g. SLAM
- GP practice code

The information should be provided to the commissioner in a form that is compliant with Information Governance requirements.

4.5 Infection control

Notwithstanding main contract clause SC21, the Provider will ensure that it has appropriate arrangements for infection control and decontamination. The Provider is required to provide the services in accordance with the National Institute of Health and Clinical Excellence (NICE) guidelines on infection control "Prevention of healthcare associated infections in primary and community care, June 2003" and The Health Act 2008, Code of Practice for Infection Prevention and Control of Healthcare associated Infections (DH 2008)

The Provider will:

- Comply with the Primary Care antibiotic Guidelines;
- Take measures to minimise the risk of infection and the spread of infection between patients and staff, including any health professional which the Provider has asked to carry out clinical activity;
- Ensure the environment and equipment used for patient care is fit for purpose and where required decontaminated in line with national and local policies; and
- Ensure all staff receive suitable and sufficient training to ensure they are complying with local and national recommendations and are able to reduce the risk of transmissions of infection by good clinical practice and treatment.

The Provider will be required to participate with random unannounced audits' if required by the commissioner's e.g. environmental cleanliness and infection prevention and control. They must comply in full with recommendations made subsequent to these visits.

The Provider should demonstrate good infection control and hygiene practice and must ensure evidence based policies and guidelines in place to facilitate this. All staff will facilitate and co-operate with the Commissioners' Infection Control Teams in monitoring, audit and investigation (including Root Cause Analysis) of the environment, patient outcomes and practices to ensure high standards are maintained.

5. Applicable Service Standards

5.1 Applicable national standards (eg NICE)

Department of Health, 2011. *NHS Outcomes Framework 2012 to 2013.* [Online] Available at: https://www.gov.uk/government/publications/nhs-outcomes-framework- 2012-to-2013

General Medical Council, 2008. *Consent guidance: patients and doctors making decisions together.* http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

General Medical Council, 2013. *Delegation and referral.* http://www.gmc-uk.org/guidance/ethical_guidance/21187.asp

General Medical Council, 2013. *Good practice in prescribing and managing medicines and devices.* http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp

National Institute for Care and Excellence, 2008; updated 2012. Macular Degeneration (age-related) - ranibizumab and pegaptanib: guidance (TA155). http://www.nice.org.uk/nicemedia/live/12057/41719/41719.pdf

National Institute for Care and Excellence, 2013. Aflibercept solution for injection for treating wet

age-related macular degeneration.
http://www.nice.org.uk/nicemedia/live/13720/63978/63978.pdf

5.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

The Provider shall ensure the service meets the standards and requirements of The Royal College of Ophthalmologists

- The Royal College of Ophthalmologists, 2009a. *Age Related Macular Degeneration Guidelines for Management,* London: The Royal College of Ophthalmologists.
- The Royal College of Ophthalmologists, 2009b. *Guidelines for Intravitreal Injections Procedure,* London: The Royal College of Ophthalmologists.
- The Royal College of Ophthalmologists, 2009c. *The Use of Bevacizumab (Avastin) in AMD,* London: The Royal College of Ophthalmologists.
- The Royal College of Ophthalmologists, 2013. College Statement on Intra-Ocular Injections by Non-Medical Health Care Professionals (HPCs), London: The Royal College of Ophthalmologists.

5.3 Applicable local standards

See Schedule 4 Quality Requirements for KPI's

Development of patient centred service

Clinical services must be patient-focused and of a high quality resulting in high patient satisfaction levels, delivered in an environment that provides a positive patient experience using correct clinical facilities by appropriately qualified clinical staff. The Provider will need to ensure that services provision is adapted to meet the needs of vulnerable people, people with learning and physical difficulties and mental health needs.

The Provider will be required to demonstrate:

- How it aims to make services accessible and convenient for all patient groups;
- How it will ensure that its services are appropriate and responsive to patient needs of all patient groups;
- How it will involve all patient groups in delivering or designing its services; and
- How progress in the above areas will be monitored and evaluated

Compliance with policies and procedures

The Provider must comply with the following:

- Standards for Better Health (of most up-to-date equivalent);
- The Commissioner's policies on consent and complaints;
- Relevant legal and regulatory requirements in relation to the provider and the service provision
- Health and Safety legislation & associated legislation;
- Management of Medical Devices Policy;
- Incident Reporting Procedure; and
- Serious Untoward Incident Reporting Policy

Governance

The provider shall put into place a system that demonstrates the governance arrangements for the organisation including managing risk.

Clinical Governance

Notwithstanding main contract clause GC15, the Provider is expected to demonstrate robust clinical governance arrangements in line with the 7 recognised pillars to ensure the safety, efficacy and a positive patient experience of the service is maintained.

All significant patient safety incidents will be identified, investigated and reported to the commissioners in line with the national framework for Serious Incidents Requiring Investigation.

The Provider must have in place arrangements for effecting change to continuously drive improvements and demonstrate that lessons learnt from such events have been shared throughout the organisation.

The Provider is required to obtain an appropriate level of indemnity for clinical negligence based on the activities and services to be provided under the contract that is in line with the local standards.

The Provider should comply with all national statutory employment requirements and related NHS policy.

The Provider is required to have a detailed Clinical Governance policy, which is regularly and systematically reviewed. The system must demonstrate a chain of responsibility and accountability from the individual providing care to the patient to Board Level, and evidence policies and procedures that give assurance that care is safe and effective.

In addition, the Provider will have policies to include:

- Patient and Public Involvement and Experience;
- Risk Management and Incident Reporting;
- Clinical Effectiveness (including research);
- Information Governance;
- Education and Training including Medical Revalidation;
- Complaints and concerns;
- Serious Incidents Requiring Investigate (SIRI) and Significant Events; and
- Equality and Diversity.

All policies shall have the necessary equality impact assessments.

Clinical leadership will be supported and developed in all disciplines working within the service. The Provider Board should include a Medical Director who will be responsible for:

- The clinical governance framework; and
- Provision of medical leadership required for delivery of the services at a local level.

All consultation activity will be audited and this audit should be fed into individual staff development and should utilise the Royal College of Ophthalmologists (RCOphth) or General Practitioners (RCGP) toolkit or an agreed equivalent.

The Provider will be appropriately registered with the Care Quality Commission and any other relevant body and will inform the CCG of any restrictions on that registration.

Contract Monitoring

Notwithstanding the main contract provisions (SC2/SC3/GC9) the Provider must provide all services in accordance with the Department of Health accreditation standards and robust information systems must be in place to demonstrate compliance with those standards.

The Provider will provide robust details of historic and current activity and financial profiles so that plans can be established to manage any unplanned and planned changes to service provision.

A regular programme of contract review meetings, supported by monthly activity reports, will be held between the CCG and the Provider.

The purpose of the meetings will be to monitor and review:

- The contractors performance against the service specification;
- The delivery of the quality standards;
- Changes in the pattern of service;
- Activity levels;
- The financial arrangements where appropriate;
- Use of contingency plans; and
- Any other relevant contract issues / problems.

The provider shall ensure a detailed patient level dataset is submitted on a monthly basis, with the fields and format agreed with the commissioner, and avoiding free text entry. As a minimum the dataset shall include (as applicable to the part of the service (Tier 2/Macular):

- On referral
    - Patient NHS number * subject to Information Governance requirements
    - Patient's registered GP practice code
    - Name of referrer
    - GOC registration number of referrer
    - Date of referral
    - Date patient seen
    - Diagnosis (ICD10)
    - Eye (left, right, both)
    - Visual acuity (letters)
    - Date initial care plan completed with the patient
    - Shared Decision Making discussion (SDM) with the patient (Y/N)
- Routine follow up
    - Planned date for follow up
    - Actual date of follow up
    - Visual acuity at follow up attendance (letters)
    - OCT shows active disease (Y/N)
    - OCT central subfield thickness (microns)
    - If OCT positive, date of subsequent injection
    - If Yes and procedure not performed state the reason
    - Procedure operator national / professional code
    - Review SDM with patient (Y/N)
    - Time spent in department (minutes)
    - DNA or cancellation; reason
- Cease to treat
    - Date of decision to cease treatment
    - VA at cease to treat
    - Patient choice (Y/N + explanation)
    - Provider choice (Y/N + explanation_
    - Meets RCOphth cease to treat criteria (Y/N)
- Patient experience
    - Complaints
    - Patient Experience feedback information

This patient level dataset shall be aggregated up on a monthly basis to provide the following "Activity Reports" including (but not limited to):

- Total number of patients referred into the macular service;
- Numbers of conditions presented (appropriately coded);
- Number of sessions per month per service;

- Number of patients seen within each session per service;
- Number of new appointments within each session per service;
- Number of follow-up appointments within each session per service;
- Number of treatments administered (appropriately coded);
- Number of patients referred on to secondary care;
- Number of DNAs;
- Number of patients discharged at first appointment;
- Waiting times; and
- Number of Cancelled / re-scheduled appointments

This is not an exhaustive list and will be developed further with the successful provider.

The form of contract will be the 2016/17 NHS Standard Contract. The service will be paid for on a price and activity basis.

Insurance

It is the responsibility of the provider to have the following insurance and maintain all insurance policies. The provider must provide details of the following insurance cover:

- Employers liability; £5m
- Public and product liability; £10m
- Clinical negligence; £10m
- Buildings and/or property insurance (as appropriate to facilities)
- Contents insurance (as appropriate to facilities)

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5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

Notwithstanding the provisions of Schedule 4 parts A-D

Registration with the Care Quality Commission (CQC)

The CCG requires evidence of compliance with CQC registration including as a minimum evidence of robust policies / procedures for the following::

Safety Domain

Risk Management

1. An annual risk assessment is carried out for the service based on the NPSA Risk Assessment Programme to include:
   a. The level and management of risk is identified for all risks
   b. All high level risks are recorded on the organisational risk register and managed at board level or equivalent
   c. All significant incidents are recorded and acted on
   d. All risk data are analysed and reviewed together, to determine and act on trends
2. All SUIs are reported to the CCG, with details of investigation, recommendations and actions taken.
3. A system is in place to manage and act on patient safety notices (The Provider will be included in the CCG's system of alerts for patient safety notices).

Infection Control

4. Medical devices are used and decontaminated according to regulations.
5. All medicines are handled safely and securely.

6. The organisation has, and carries out, an action plan to implement the hygiene code, including necessary audits and improvements.
7. If controlled drugs are used by a service, CD regulations are followed, a self – assessment is carried out and any highlighted actions identified and completed.
8. Waste management is carried out in line with most recent regulations.

Clinical And Cost Effectiveness Domain

Clinical and Cost Effectiveness

9. All relevant NICE guidance is reviewed and implemented where appropriate, with decisions on implementation documented.
10. The organisation has a system to identify areas for audit which is informed by organisational priorities, and includes review of referral criteria and demand management.
11. Audits are completed with recommendations carried out and re-audit completed.

Staff training, development and supervision

12. All staff have annual appraisal and development plans that are monitored.
13. Agreed mandatory training is available to staff and is monitored and action taken to ensure attendance.
14. All staff have appropriate training for the work being carried out, including induction.
15. Staff have opportunity for reflective learning / clinical supervision.
16. All staff are appropriately recruited, trained, qualified and registered for the role undertaken.
17. Any delegation is carried out in line with agreed delegation guidance.

Partnership working

18. The organisation works with other organisations to ensure effective collaboration to meet patient needs.

Governance Domain

Clinical Governance

19. The organisation has a clinical governance lead.
20. There are systems for ensuring sound clinical and corporate governance.

Information Governance

21. A robust records management system is in place, covering all stages of records management, and data confidentiality issues.

Patient Focus Domain

22. There is a Consent to Treatment policy that is fit for purpose and audited, and supports the process for obtaining valid and informed consent from patients.
23. Clear and up-to-date patient information is available for all services.
24. The organisation has a procedure for complaints which is easily available to patients.

Accessible and Responsive Care Domain

25. Patients' views are sought at any service change and cover information, waiting times and access, quality of care, patient's understanding and other priority areas. The results of the survey are discussed acted on and feedback provided to patients.
26. Equality and diversity, including accessibility, are discussed and acted on for all services. These include both staff and patients.
27. The provider will co-operate and participate in Healthwatch work around assessing accessibility and responsiveness including allowing access for service reviews.

Care Environment and Amenities Domain

35. Environments used by the organisation are clean, safe, secure and fit for purpose.

Public Health Domain

28. The organisation takes opportunities to promote and improve health and identify and address health inequalities.
29. The organisation, together with other local organisations, has a plan to cover emergency situations (including business continuity).

All commissioned organisations are required to:

1. Make a self-assessment of compliance against both CQC and additional agreed quality indicators, e.g. controlled drugs, information governance.
2. Report to the CCG on CQC and agreed quality indicators every three months. This would involve an in-depth review of all indicators annually, and a brief three-monthly evidence based overview assurance report showing lapse where standards are not met. Where there is lapse a Non Compliance Action Plan will be completed and submitted with the report.
3. Report all Serious Untoward Incidents (SUI's) to the CCG, and provide details of investigations, recommendations, actions taken and learning from the investigations.
4. Carry out and report on clinical audits to show implementation of relevant national guidance and organisational policies, and any areas where the CCG has concerns.
5. Allow relevant CCG staff to carry out inspections to determine compliance with elements of the contract with the CCG, and with CQC.

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

6. Location of Provider Premises

The Provider's Premises:

The provider will be required to demonstrate the locations in Greater Preston, Chorley & South Ribble CCG footprints from where it will provide this service. The service should be delivered from registered healthcare facilities within the Preston, Chorley & South Ribble CCG boundaries and it is the expectation that there will be a minimum offer of at least one site in each locality (i.e. at least 3).

The location(s) of premises should be accessible by public transport and should have parking facilities. Premises should also be accessible by patient transportation service vehicles for those patients with a medical need for transportation.

All services and facilities must comply with the Disabilities Discrimination Act 1995 relating to access arrangements for people with hearing and visual impairments.

Providers shall ensure that the facilities provided should incorporate suitable waiting areas, consultation and examination rooms, furniture, fittings and equipment as required to provide a safe service. Equipment includes all computer hardware and software required to operate the service.

There must be clear signage in place to ensure easy access for patients.

All premises should meet statutory requirements and follow best practice guidance.

National Building Requirements define the standards of the above facilities and will be complied with.

Premises must:

- Facilitate the effective and efficient delivery of the services to patients;
- Deliver a patient experience and environment that is in line with NHS guidelines;
- Enable the services to be delivered conveniently to patients and NHS standards; and
- Take into account the mobility for the local population and the availability of local public transport to maximise access to patients.

All parts of the premises in which the service operates must be suitable for the purpose, kept clean and maintained in good physical repair and condition. In particular, the physical environment must comply with Infection Control in the Built Environment (NHS Estates: 2002). The document specifically includes (but is not limited to) the following aspects to reduce risks of infection:

- Sizing / space;
- Clinical sinks;
- Ancillary areas;
- Engineering services which incorporates advice on ventilation, lighting, water supply;
- Storage;
- Finishes, floors, walls, ceilings, doors, windows, fixtures and fittings;
- Decontamination;
- Laundry and linen;
- Waste – segregation, storage and disposal; and
- Workflow

Where premises are used to deliver surgery of procedures the provider must be able to demonstrate that the premises are fully compliant with the relevant regulations and legislation.

The CCG reserve the right to inspect the services premises / records and policies at any time in accordance with main contract clause GC15.2.

7. Individual Service User Placement