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Welsh Health Specialised Services Committee (WHSSC)

Specialised Services
Service Specification: CP238

The Welsh Artificial Eye Service (WAES) (All Ages)

December 2022

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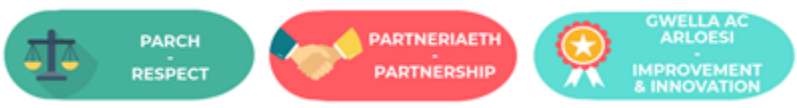

Document information	
Document purpose	Service Specification
Document name	The Welsh Artificial Eye Service (WAES) (All Ages)
Author	Welsh Health Specialised Services Committee
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Commissioning Team	Neurosciences and Long term Conditions
Target audience	Chief Executives, Medical Directors, Directors of Finance, Directors of Therapies, Directors of Planning, Orbital Prosthetists, NHS Wales Artificial Limb and Appliance Centre
Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this document
Document No	CP238
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Contents

Statement

Welsh Health Specialised Services Committee (WHSSC) will commission the Welsh Artificial Eye Service (WAES) for people of all ages in accordance with the criteria outlined in this specification.

In creating this document WHSSC has reviewed the requirements and standards of care that are expected to deliver this service.

Disclaimer

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this document.

This document may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this document.

1. Introduction

This document has been developed as the Service Specification for the planning and delivery of the Welsh Artificial Eye Service for people of all ages resident in Wales. This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

1.1 Background

An artificial eye is a custom-made medical device manufactured from medical grade polymethylmethacrylate (PMMA) that replaces an absent living eye or covers a damaged eye to improve cosmesis, fill the volume deficit and maintain the shape of the eye socket. Each artificial eye is custom-made and manufactured from a prescription designed by an Ocularist or Orbital Prosthetist in accordance with Medical Device Regulations (MDR).

Loss of an eye or eyes is a life-long condition, but it should be recognised that sight loss can be managed effectively through specialised rehabilitation services and re-enablement support and can provide the individual patient with improvements in quality of life and independence.

1.2 Current Service

The Wales Artificial Eye Service (WAES)[1] is the single national provider of the artificial eye service for Wales. WAES is commissioned to provide an artificial eye for psychological, social and cosmetic purposes to people across a number of sites in Wales.

WAES is delivered by the Artificial Limb and Appliance Service (ALAS)[2] in Cardiff and Vale University Health Board, and provides a service to around 1,750 active patients across Wales.

There are approximately 80 new referrals to the service per year, and these are broadly received following, trauma, surgery, cancer or a congenital condition of the eye.

The main hub is based at:

- Artificial Limb and Appliance Service (ALAS)
  18-20 Fairwater Road
  Llandaff
  Cardiff
  CF5 2YN

[1] Artificial Eye Service - Cardiff and Vale University Health Board
[2] Artificial Limb and Appliance Service - Cardiff and Vale University Health Board

Outpatient clinics are held in:

- Nevill Hall Hospital, (Oral Surgery Dept)
  Brecon Road
  Abergavenny
  NP7 7EG

- Posture and Mobility, Wrexham (ALAS)
  Gate 7, Wrexham Maelor Hospital
  Croesnewydd Road
  Wrexham
  LL13 7NT.

- Abergele Hospital – Stanley Eye Unit
  Abergele Hospital
  Llanfair Road
  Abergele
  Conwy
  LL22 8DP

- Colwyn Bay Community Hospital
  Hesketh Road
  Colwyn Bay
  LL29 8AY

- Bro Ddyfi Hospital Machynlleth
  Heol Maengwyn
  Machynlleth
  Powys
  SY20 8AD

1.3 Aims and Objectives

The aim of this service specification is to define the requirements and standard of care essential for delivering the Wales Artificial Eye Service.

The objectives of this service specification are to:

- detail the specifications required to deliver the Wales Artificial Eye Service for people of all ages and resident in Wales
- ensure minimum standards of care are set for the Wales Artificial Eye Service
- ensure equitable access to the Wales Artificial Eye Service
- identify centres that are able to provide an Artificial Eye Service for Welsh patients
- improve outcomes for people accessing the Wales Artificial Eye Services.

1.4 Relationship with other documents

This document should be read in conjunction with the following documents:

- **NHS Wales**
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).

- **Relevant NHS England policies**
  - National Artificial Eye Service Specification (all Ages), D01/S/e, 2013

2. Service Delivery

The Welsh Health Specialised Services Committee will commission the Welsh Artificial Eye Service for people of all ages and resident in Wales, in-line with the criteria identified in this specification.

2.1 Access Criteria

The service is for individuals of any age requiring any type of artificial eye prosthesis in order to improve the aesthetic appearance of a missing, damaged or disfigured eye and to support the socket in order to maintain optimum cosmesis. The conditions this group encompasses include cancer, trauma or congenital eye diseases.

Patients can access the service in a number of ways:

- **Pre-operatively**
  Consultation can be arranged with appropriate members of the WAES Team.

- **Established patients**
  They will require input from the service in order to review and maintain their artificial eye and check the health of their eye socket or phthisical (damaged, unsighted eye).

- **Changing needs**
  Children, young adults and other patients with more complex problems require a more flexible model of care which may require more frequent appointments and artificial eye replacement based on their individual needs.

2.2 Service description

In addition to the standards required within the Contract, specific quality standards and measures will also be expected. The provider should also meet the standards as set out below.

Facilities and equipment

The service should ensure:

- There is a lathe for polishing and the maintenance of ocular prostheses and, depending on the size of the service they will require polymerising equipment for the manufacture of eyes.
- There are clinic rooms/lab space available, with separate rooms for clinical assessment and manufacturing. Clinical assessment rooms should have a good proportion of natural light to ensure correct eye colour match.

- That individual adult and child clinics are held, ensuring there is no mix of adult or child clinics. All children should be accompanied by a parent, guardian or carer.

Manufacture of artificial eye prosthesis

The service should ensure:

- The manufacture of the artificial eye uses the same standard production process, fitting and materials that are accepted as appropriate by the dental manufacturing industry. These processes should be in line with the National Artificial Eye Service in Blackpool[3] and the service methods should be checked against them on an ongoing basis.
- The evidence base for design and manufacture of artificial eye prosthesis are as required by the Medicines and Healthcare Products Regulatory Agency (MHRA)[4].

Essential staffing

- Ocularist
- Orbital Prosthetist
- Administration to support the process of new referrals, and to allocate appointments etc.

The exact number of staff will be dependent on the geographical area covered and the number of active patients.

2.3 Interdependencies with other services or providers

There are no interdependencies with the Welsh artificial eye service.

Related services include:

- The National Artificial Eye Service (NAES) [3] in Blackpool which is used for the manufacture of the majority of eyes.
- Ophthalmology Consultants and ophthalmic departments of referring hospitals.
- Ocular Plastics Team
- Opticians
- General Practitioners.
- Other ALAS services.

[3] NAES – National Artificial Eye Service
[4] Services and information - Medicines and Healthcare products Regulatory Agency - GOV.UK

2.4 Acceptance Criteria

The proposed service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.5 Patient Pathway (Annex i)

The service will accept referrals from primary or secondary care services.

Patients will generally be under the care of a Consultant Ophthalmologist or Oculoplastic surgeon. An overview of the patient pathway is provided in Annex i.

2.6 Service provider/Designated Centre

- Artificial Limb and Appliance Centre
  Cardiff and Vale University Health Board
  18-20 Fairwater Road
  Llandaff
  Cardiff
  CF5 2YN

2.7 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

3. Quality and Patient Safety

The provider should work to written quality standards and provide monitoring information to the lead commissioner. The quality management systems should be externally audited and accredited.

The centre should enable the patients, carers and advocates informed participation and to be able to demonstrate this. Provision should be made for patients with communication impairment and for children, teenagers and young adults.

3.1 National Standards

- As a manufacturer of medical devices, the WAES must maintain compliance with the MDR and certification to the ISO9001 and or ISO 13485 standard. There are a number of provisions within this standard which should be managed including the necessity to have an ongoing internal audit schedule and various patient satisfaction measures.

3.2 Other quality requirements

- The provider should have a recognised system to demonstrate service quality and standards.
- The service should have detailed clinical protocols setting out nationally (and local where appropriate) recognised good practice for each treatment site.
- The quality system and its treatment protocols should be subject to regular clinical and management audit.
- The provider is required to undertake regular patient surveys and develop and implement an action plan based on findings.
- The provider is required to monitor various manufacturing processes to ensure ongoing safety and traceability of all items produced.

4. Performance monitoring and Information Requirement

4.1 Performance Monitoring

WHSSC will be responsible for commissioning services in line with this service specification. This will include agreeing appropriate information and procedures to monitor the performance of organisations.

For the services defined in this service specification the following approach will be adopted:

- Service providers to evidence quality and performance controls
- Service providers to evidence compliance with standards of care.

WHSSC will conduct performance and quality reviews on an annual basis.

4.2 Key Performance Indicators

The providers are expected to monitor against the full list of Quality Indicators derived from the service description components described in Section 2.2.

The provider should also monitor the appropriateness of referrals into the service and provide regular feedback to referrers on inappropriate referrals, identifying any trends or potential educational needs.

In particular, the provider will be expected to monitor against the target outcomes set out in Annex ii.

4.3 Date of Review

This document is scheduled for review before December 2025, where we will check if any new evidence is available.

If an update is carried out the policy will remain extant until the revised policy is published.

5. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

6. Putting Things Right

6.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

6.2 Individual Patient Funding Request (IPFR)

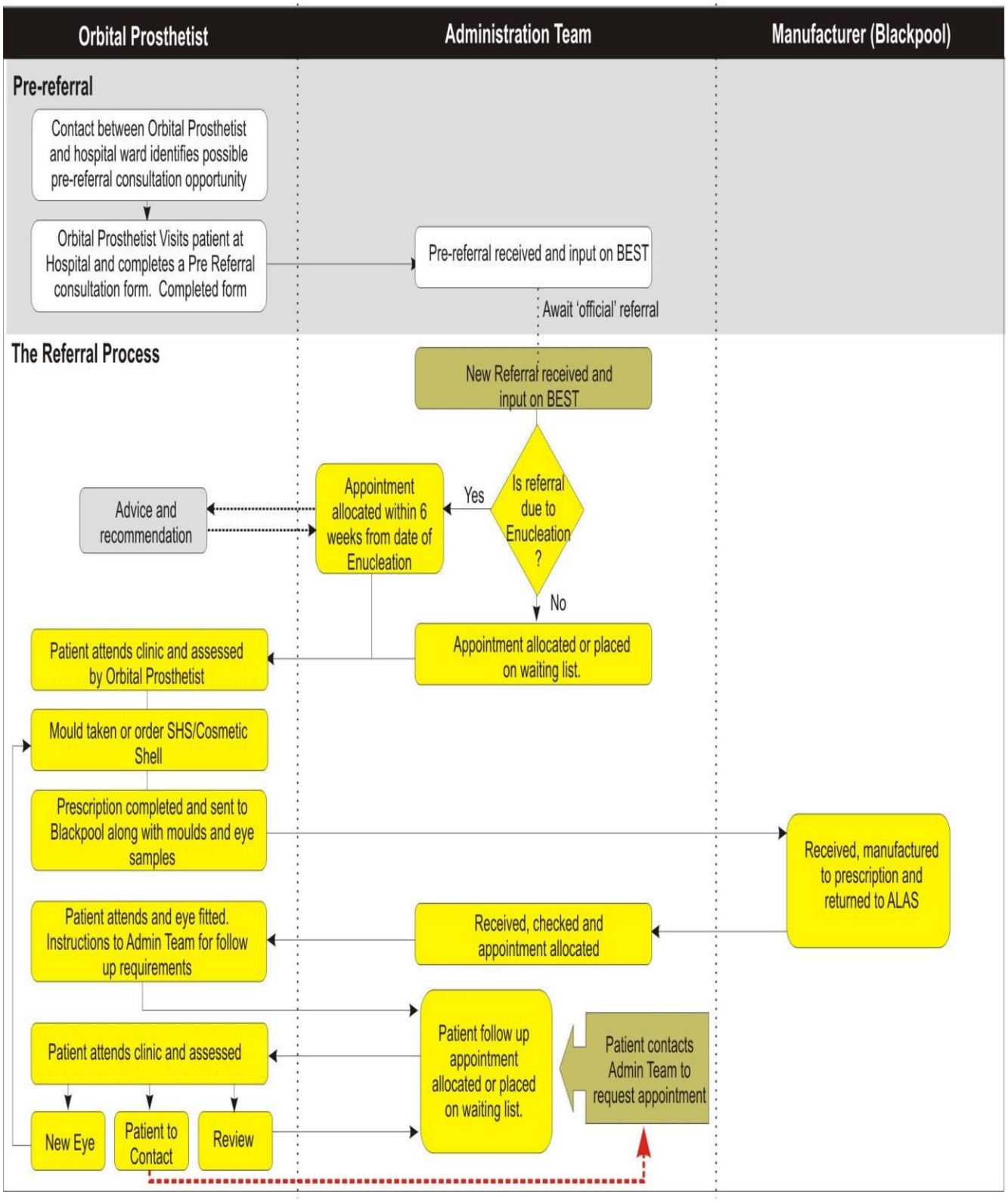
If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

Annex i Patient Pathway



Annex ii Key Performance Indicators

	KPI	Target
1.	Referral acknowledgement	To be agreed
2.	Appropriate referral	5 days
3.	Referral screening and pathway recommendation	5 days
4.	Referral to first assessment (enucleation and evisceration pathways only)	2 weeks
5.	Referral to One stage Mould Eye (OME) assessment	8 weeks
6.	Referral to manufacture completion	
7.	Referral to issue	14 weeks
8.	First assessment to OME assessment	18 weeks (80%) 26 weeks RTT (95%)
9.	OME assessment to manufacture completion	6 weeks
10.	Manufacture completion to issue	4 weeks
11.	Request for check-up/review	6 weeks

Annex iii Abbreviations and Glossary

Abbreviations

IPFR Individual Patient Funding Request

WHSSC Welsh Health Specialised Services

WAES Welsh Artificial Eye Service

NAES National Artificial Eye Service

OME **One Stage Mould Eye**

BEST **Bringing Equipment Services Together**

MDR **Medical Device Regulation**

Glossary

Individual Patient Funding Request (IPFR)

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

Welsh Health Specialised Services Committee (WHSSC)

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.

Cosmesis

Surgical correction of a disfiguring defect, or the cosmetic improvements made by a surgeon following incisions.

OME

One Stage Mould Eye – the appointment where the clinic work for making a custom-made eye is done. An impression of the socket is taken, a wax template is sculpted to fit the socket and the colour is matched to the patient's remaining eye. The custom-made prosthesis is manufactured from this template and colour prescription

Ocularist

An autonomous practitioner who works in a clinical setting to prescribe, design and fit ocular prostheses as well as hand painting and manufacturing them. The Ocularist is responsible for the whole process from raw material to finished prosthesis. Fits both artificial eyes and cosmetic shells to adults and children.

Orbital Prosthetist

An autonomous practitioner who works in a clinical setting to prescribe, design and fit ocular prostheses, which are hand-painted and manufactured in acrylic by an Orbital Technician from a prescription provided by the Orbital Prosthetist. This is achieved by taking an impression of the eye socket and sculpting a wax pattern to fit and selecting colour patterns.

Active patient

A patient having contact with WAES within 3 years.

Artificial Eye/orbital prosthesis

A custom-made medical device manufactured from medical grade polymethylmethacrylate (PMMA) that replaces an absent living eye to improve the cosmesis, fill the volume deficit and maintain the shape of the eye socket. Each artificial eye is bespoke and manufactured from a prescription designed by an Ocularist or Orbital Prosthetist in accordance with Medical Device Regulations (MDR).

Phthisical

A damaged unsighted eye.

ISO9001 standard

The international standard that specifies requirements for a quality management system (QMS). Organisations use the standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements.

ISO 13485

A stand-alone QMS standard, derived from the internationally recognized and accepted ISO 9000 quality management standard series. ISO 13485 adapts the previous version of ISO 9001, ISO 9000:2008 process-based model for a regulated medical device manufacturing environment.

Medical Device Regulation (MDR)

This guidance provides information on the UK system, including, getting devices certified, conformity marking devices and registering devices with the Medicines and Healthcare Products Regulatory Agency (MHRA).

Medicines and Healthcare Products Regulatory Agency (MHRA)
The MHRA is responsible for regulating the UK medical devices market.

BEST
Bringing Equipment Services Together is a Patient, Equipment and Ordering software data base used by the