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The Welsh Artificial Eye Service (WAES) (all ages)

Service Specification: SS238

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Abbreviations

BEST	Bringing Equipment Services Together
IPFR	Individual Patient Funding Request
MDR	Medical Device Regulation
NAES	National Artificial Eye Service
NWJCC	NHS Wales Joint Commissioning Committee
OME	One Stage Mould Eye
WAES	Welsh Artificial Eye Service

Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission the Welsh Artificial Eye Service (WAES) service in accordance with the criteria outlined in this specification.

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

Welsh Language

NWJCC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the [Welsh Language Act \(1993\)](#), the [Welsh Language \(Wales\) Measure 2011](#) and the [Welsh Language Standards \(No.7\) Regulations 2018](#).

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience, the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this, NWJCC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered and people have access to either a translator or 'Language-line' if requested. Where possible, links to local teams should be maintained during the period of care.

Decarbonisation

NWJCC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the NWJCC commitment.

Disclaimer

NWJCC assumes that healthcare professionals will use their clinical judgement, 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.

NWJCC disclaims any responsibility for damages arising out of the use or non-use of this policy.

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 NHS Wales Joint Commissioning Committee (NWJCC) and applies to residents of all seven Health Boards in Wales.

1.1 Background

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 1,500 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.

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 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

¹ [Artificial Eye Service - Cardiff and Vale University Health Board](#)

² [Artificial Limb and Appliance Service - Cardiff and Vale University Health Board](#)

- identify centres that are able to provide an Artificial Eye Service for Welsh patients
- improve outcomes for people accessing the Wales Artificial Eye Services.

1.3 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 NHS Wales Joint Commissioning Committee will commission the service of Welsh Artificial Eye Service (WAES) for people of all ages 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 phyhisical (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.

2.2.1 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.

2.2.2 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 Blackpool³ 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.

2.2.3 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 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 Transition Arrangements

Transition arrangements should be in line with [Transition from children's to adults' services for young people using health or social care services NICE guidance NG43 and the Welsh Government Transition and Handover Guidance](#).

Transition involves a process of preparation for young people and their families for their transition to adulthood and their transition to adult services. This preparation should start from early adolescence 12-13 year olds. The exact timing of this will ideally be dependent on the wishes of the young person but will need to comply with local resources and arrangements.

The transition process should be a flexible and collaborative process involving the young person and their family as appropriate and the service.

The manner in which this process is managed will vary on an individual case basis with multidisciplinary input often required and patient and family choice taken into account together with individual health board and environmental circumstances factored in.

2.6 Patient Pathway (Annex i)

The service will accept referrals from primary or secondary care services, the completed referral form can be submitted by electronically via email or by post to the service. 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.

2.7 Service provider/Designated Centre

The main hub is based at:

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

Outpatient clinics are held in:

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

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

Colwyn Bay Community Hospital
Hesketh Road
Colwyn Bay
LL29 8A

Glangwili Hospital
Dolwili Road
Carmarthen
SA31 2AF

Bro Ddyfi Hospital Machynlleth
Heol Maengwyn
Machynlleth
Powys
SY20 8AD

Keir Hardie University Health Park
Merythr Tydfil
CF48 1B

Specialist Rehabilitation Centre
Morrison Hospital
Swansea
SA6 6LG

2.9 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

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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: [Individual Patient Funding Requests](#)

3. Quality and Patient Safety

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

The centre must enable the patients, carers and advocates informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties 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 will have a recognised system to demonstrate service quality and standards
- the service will 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 will 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

4. Performance Monitoring and Information Requirement

4.1 Performance Monitoring

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

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

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

NWJCC will conduct performance and quality reviews on an annual basis

4.2 Key Performance Indicators

The providers will be 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.

4.3 Date of Review

This document is scheduled for review every three years, unless information is received which indicates that the policy requires revision.

If an update is carried out, this version of the policy will remain extant until the revised policy is published.

5. Equality Impact and Assessment

The Equality Impact Assessment (EIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable NHS Wales Joint Commissioning 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 NWJCC.

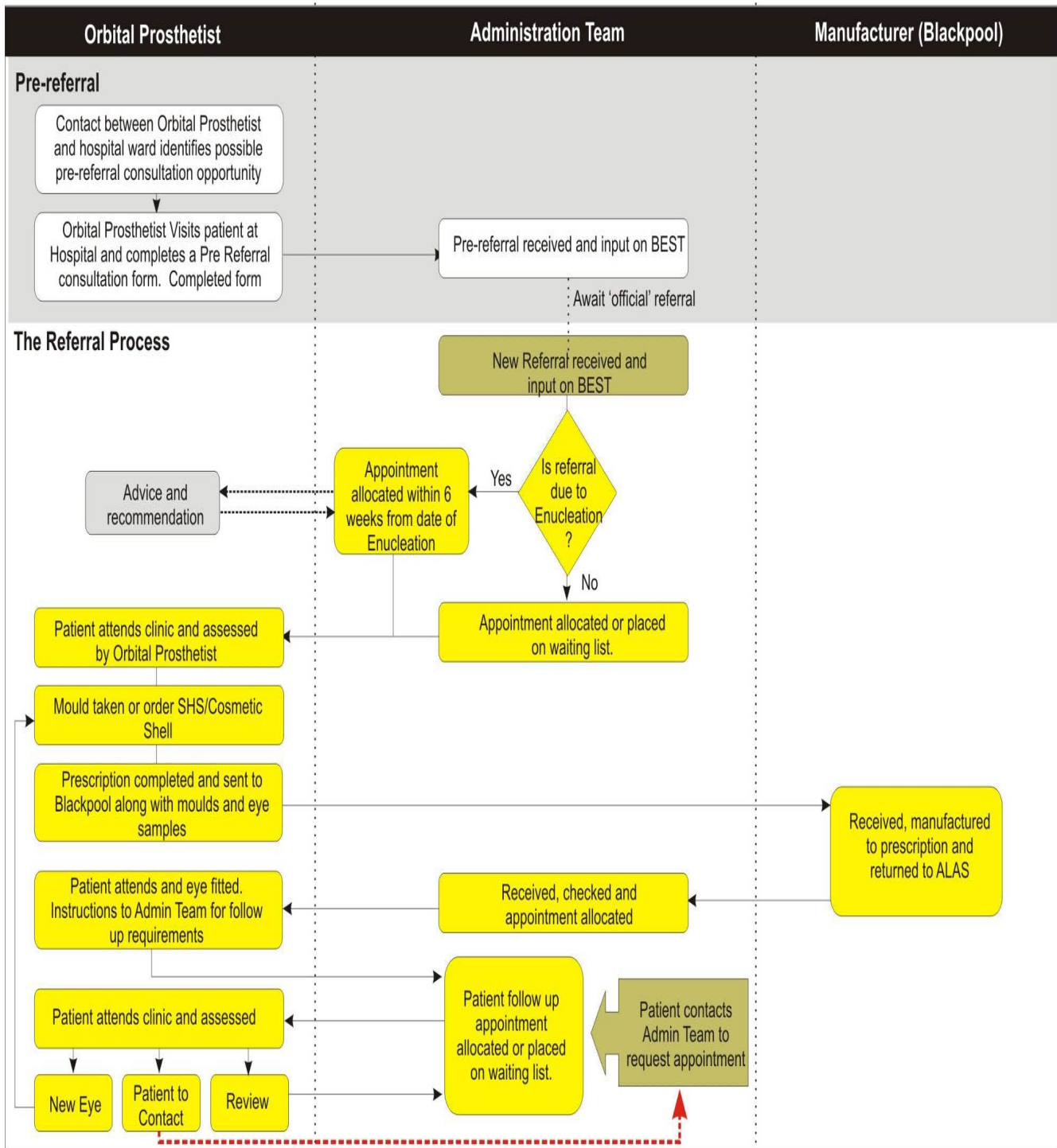
6.2 Individual Patient Funding Request (IPFR)

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 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: [Individual Patient Funding Requests](#).

Annex i Patient Pathway



Annex ii Key Performance Indicators

	KPI	Target
1.	Referral acknowledgement/referral returned if inappropriate or further information is required	10 days
2.	Appropriate referral	5 days
3.	Referral screening and pathway recommendation	5 days
4.	Acceptance to first assessment (enucleation and evisceration pathways only)	2 weeks
5.	First assessment to OME assessment	18 weeks (80%) 26 weeks RTT (95%)
6.	OME assessment to manufacture completion	8 weeks
7.	Manufacture completion to issue	4 weeks
8.	Request for check-up/review	6 weeks

Annex iii Codes

The list of ICD codes is indicative and is not exhaustive. Additional codes may be used for contract monitoring purposes, furthermore some codes may cover indications not included within this policy.

Code Category	Code	Description
ICD 10	H00–H59	Diseases Of the Eye and Adnexa
ICD 10	S05-90	Unspecified injury of unspecified eye and orbit

Annex iv Glossary

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).

BEST

Bringing Equipment Services Together is a Patient, Equipment and Ordering software data base used by the ALAS services in Wales.

Cosmesis

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

Individual Patient Funding Request (IPFR)

An IPFR is a request to NWJCC to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

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.

NHS Wales Joint Commissioning Committee (NWJCC)

NWJCC is a joint committee of the seven local health boards in Wales. The purpose of NWJCC is to ensure that the population of Wales has fair and equitable access to the full range of Tertiary Services. NWJCC ensures that services within our portfolio 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.

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.

Phthisical

A damaged unsighted eye.

Contact Us

If you have a question related to this document you can contact us using one of the methods outlined below.

If you would like this document in an alternative format and/or language, please contact us for assistance.

Email:

NWJCC consultation mailbox – nwjccconsultation@wales.nhs.uk

Telephone:

General Enquiries – 01443 433112

Website:

[Contact us - NHS Wales Joint Commissioning Committee](#)

Writing:

If you wish to contact the NHS Wales Joint Commissioning Committee, you can write to us at one of our locations below, we welcome correspondence in Welsh or English:

South Wales Offices

Unit 1, Charnwood Court, Heol Billingsley, Nantgarw, CF15 7QZ

Unit G1 The Willowford, Main Avenue, Treforest Industrial Estate, Pontypridd, CF37 5YL

North Wales Offices

Unit 3, Media Point - Unit 3, Mold Business Park, Mold, CH7 1XY

Preswylfa, Hendy Road, Mold, CH7 1PZ