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Welsh Health Specialised
Services Committee (WHSSC)

Specialised Services Policy Position PP103

Everolimus for the prevention of organ rejection following heart transplantation

*July 2019
Version 1.0*

Document information

Document purpose	Policy Position
Document name	Everolimus for the prevention of organ rejection following heart transplantation
Author	Welsh Health Specialised Services Committee
Publication date	July 2019
Commissioning Team	Cardiac
Target audience	Chief Executives, Medical Directors, Directors of Finance, Chief Pharmacists
Description	NHS Wales will not routinely commission this specialised service in accordance with the criteria described in this policy
Document No	PP103

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1. Policy Statement

Welsh Health Specialised Services Committee (WHSSC) will not routinely commission Everolimus for the prevention of organ rejection following heart transplantation for patients resident in Wales.

In creating this document WHSSC has reviewed the relevant guidance issued by NHS England and the All Wales Medicine Strategy Group (AWMSG). It has considered the place for this treatment in current clinical practice and whether the research has shown a benefit to patients. WHSSC has concluded that there is not enough evidence to make the treatment available at this time.

Plain language summary

Heart transplants

Heart transplants are performed on people in the final stages of heart disease, when no other treatments will work. After transplant, the main goal is to make the heart last as long as possible.

About current treatments

After the transplant, patients need medicines to stop the immune system 'attacking' the heart. If this happens the heart can be 'rejected'.

These medicines are called 'anti-rejection' medicines (or 'immunosuppressants'). These medicines make you more likely to get infections.

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About the new treatment

Everolimus is a new anti-rejection medicine for use after a heart transplant. Anti-bodies are an important part of the body's defence system. Everolimus works by stopping the anti-bodies growing, this stops the new heart being rejected.

Different anti-rejection medicines can be used together after transplant. Each have different side effects. Using different anti-rejection medicines together helps to reduce these side effects as much as possible. Having different combinations available helps to find the best ones to use for each patient.

Everolimus causes immunosuppression via different pathways to other treatments, and has been proposed as an alternative immunosuppressant treatment to prevent organ rejection and kidney dysfunction in patients at immunological risk following an allogeneic cardiac transplant.

There is insufficient evidence for WHSSC to routinely commission Everolimus for the prevention of organ rejection following heart transplantation

2. Aims and Objectives

This proposed policy aims to define the commissioning position of Everolimus for the prevention of organ rejection following heart transplantation on for the residents of Wales.

The objective is to ensure evidence based decisions are made on commissioning Everolimus for the prevention of organ rejection following heart transplantation for the residents of Wales.

3. Documents which have informed this policy

The following documents have been used to inform this policy:

- **All Wales Medicine Strategy Group (AWMSG) guidance**
 - All Wales Medicine Strategy Group 2015. [Everolimus, Prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a cardiac transplant](#). Ref 436. May 2015.
- **NHS England policies**
 - Clinical Commissioning Policy: [Everolimus for the prevention of organ rejection following heart transplantation](#), 16016/P, July 2016

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

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

4. Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

5. Putting Things Right

5.1 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.

5.2 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, 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](#)

6. 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.

Annex i Abbreviations and Glossary

Abbreviations

IPFR	Individual Patient Funding Request
WHSSC	Welsh Health Specialised Services
AWMSG	All Wales Medicine Strategy Group

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.