

Pwyllgor Gwasanaethau lechyd
Arbenigol Cymru (PGIAC)
Welsh Health Specialised
Services Committee (WHSSC)

# Specialised Services Commissioning Policy: CP183a

# Radiofrequency Ablation (RFA) for the Management of Barrett's Oesophagus in Adults

April 2020 Version 1.0

| Document information |  |
|----------------------|--|
| Document purpose     | Policy   |
| Document name        | Radiofrequency Ablation (RFA) for the Management of Barrett's Oesophagus in Adults   |
| Author               | Welsh Health Specialised Services Committee  |
| Publication date     | April 2020   |
| Commissioning Team   | Cancer & Blood   |
| Target audience      | Chief Executives, Medical Directors, Directors of<br>Finance, Gastroenterologists, Upper GI Surgeons,<br>Upper GI Pathologists |
| Description          | NHS Wales will commission this specialised service<br>in accordance with the criteria described in this<br>policy              |
| Document No          | CP183a   |
| Review Date          | 2024   |

# Contents

| Policy St  | tatement   | 4       |
|------------|--|---------|
| Disclair   | mer  | 4       |
| 1. Intro   | duction  | 5       |
| 1.1        | Plain Language Summary   | 5       |
|            | causes Barrett's Oesophagus?                                   |         |
| What       | are the usual symptoms?  | 5       |
| What       | are the complications?   | 5       |
| What       | is dysplasia in the oesophagus?                                | 6       |
| The a      | im of Radiofrequency Ablation (RFA)                            | 6       |
| 1.2        | Aims and Objectives  | 7       |
| 1.3        | Epidemiology   |         |
|            | Current Treatment  |         |
| 1.5<br>1.6 | Proposed Treatment<br>What NHS Wales has decided               | ۲۲<br>و |
| 1.7        | Relationship with other documents                              |         |
|            |  |         |
| 2. Criter  | ria for Commissioning  | 11      |
| 2.1        | Inclusion Criteria   |         |
| 2.2        | Exclusion Criteria   |         |
|            | Acceptance Criteria  |         |
| 2.4<br>2.5 | Patient Pathway (Annex i)                                      |         |
| 2.5        | Designated Centre(s)<br>Exceptions                             |         |
| 2.7        | Clinical Outcome and Quality Measures                          |         |
| 2.8        | Responsibilities   |         |
| 3. Evide   | nce  |         |
|            | Date of Review   |         |
| 4. Equal   | lity Impact and Assessment                                     |         |
|            | ng Things Right  |         |
|            |  |         |
|            | Raising a Concern<br>Individual Patient Funding Request (IPFR) |         |
| Annex i    | Patient Pathway  | 20      |
| Annex ii   | Checklist  | 21      |
| Annex iii  | Codes  | 22      |
| Annex iv   | Abbreviations and Glossary                                     | 23      |

# **Policy Statement**

Welsh Health Specialised Services Committee (WHSSC) will commission Radiofrequency Ablation (RFA) for the Management of Barrett's Oesophagus in Adults in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

#### Disclaimer

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

This policy 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.

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

# 1. Introduction

This policy has been developed for the planning and delivery of Radiofrequency Ablation (RFA) for the management of Barrett's Oesophagus in Adults for people resident in Wales.

# **1.1 Plain Language Summary**

### What is Barrett's Oesophagus?

The oesophagus is the muscular tube that carries food from the mouth to the stomach. Barrett's Oesophagus is a condition where the normal lining, coating the lower part of the oesophagus changes to a thin membrane like the lining of the stomach or intestine. This condition was named after a London surgeon called Norman Barrett in the 1950's, who was amongst the first to discover it.

#### What causes Barrett's Oesophagus?

The cause of the condition is not known. It is believed that many years of acid reflux of stomach contents into the oesophagus (sometimes perceived as heartburn) causes injury to the lining of the oesophagus (oesophagitis). This inflammation may lead to damage to the oesophagus cells, causing the change known as Barrett's Oesophagus. Sometimes bile-containing juices in the small intestine may work their way backwards into the stomach and oesophagus. It is possible that this mixture of stomach and intestinal juices is more damaging to the oesophagus than acid alone.

In normal circumstances the oesophagus heals and returns to normal, but sometimes the oesophagus does not heal in the usual way. How or why this change happens is not known. It appears that this change may be more common in patients who are male, and/or overweight. It has been shown that smoking can accelerate any change in Barrett's Oesophagus.

#### What are the usual symptoms?

The condition often has no symptoms, but Barrett's Oesophagus is sometimes found when a person is examined by means of an endoscopy for symptoms of heartburn and acid indigestion. Sometimes Barrett's Oesophagus is found in people undergoing endoscopy for some other reason, e.g. to investigate anaemia.

Other symptoms are those associated with reflux, such as hoarse voice and chronic cough.

## What are the complications?

Barrett's Oesophagus can rarely cause a complication. Possible complications, which are usually due to chronic reflux, include:

• Ulcers in the oesophagus

- Inflammation of the lining of the oesophagus
- Narrowing of the oesophagus
- Rarely, pre-cancerous changes and cancer of the oesophagus.

Most patients with Barrett's Oesophagus will never experience any of the above complications.

#### What is dysplasia in the oesophagus?

Dysplasia is the term used to describe cells in the lining of the oesophagus that look abnormal under a microscope, and can occur in patients with Barrett's Oesophagus. Patients with Barrett's Oesophagus typically undergo surveillance endoscopy, with multiple biopsies of the diseased tissue every six months to five years in order to detect cancer at the earliest possible tumour stage. Development of dysplastic cellular changes within the Barrett's epithelium (lining) precedes the development of cancer.

Diagnosis of Barrett's Oesophagus is confirmed through histopathology following biopsy, with intestinal metaplasia (IM) graded according to the presence or absence of dysplasia from:

- No dysplasia
- Indefinite for dysplasia
- Low-grade dysplasia (LGD)
- High-grade dysplasia (HGD)

The presence of HGD or persistent LGD can signify that the cells have the potential to become cancerous. Oesophageal cancer is a serious condition, but if changes are caught at an early stage, it can be successfully treated. Less than 1 out of every 100 people (less than 1%) in the UK have Barrett's oesophagus. And very few people with this condition develop cancer. About 3 in every 100 people (3%) who have Barrett's oesophagus will develop oesophageal cancer during their lifetime.<sup>1</sup>

#### The aim of Radiofrequency Ablation (RFA)

Dysplasia and very early oesophageal cancer affects only the cells lining the oesophagus. These abnormal cells can be destroyed by performing RFA. Once performed, the oesophagus lining is expected to heal with normal cells. By treating the abnormal cells and preventing the development of cancer, the aim is to prevent the need for major surgery.

Radiofrequency energy (radio waves) is delivered via a catheter to the oesophagus to remove diseased tissue while minimising injury to healthy oesophagus tissue. This is called ablation, which means the removal or destruction of abnormal tissue.

<sup>&</sup>lt;sup>1</sup> Macmillan Cancer Support

Welsh Health Specialised Services Committee (WHSSC) April 2020

# **1.2** Aims and Objectives

This policy aims to define the commissioning position of WHSSC on the use of RFA for people with Barrett's Oesophagus.

The objectives of this policy are to:

- ensure commissioning for the use of RFA for Barrett's Oesophagus is evidence based
- ensure equitable access to RFA for Barrett's Oesophagus
- define criteria for people with Barrett's Oesophagus to access treatment
- improve outcomes for people with in Barrett's Oesophagus.

## **1.3 Epidemiology**

Barrett's oesophagus is prevalent in 1.5-2.5% of the adult population in the UK<sup>2</sup> with around 60,000 new cases per year (annual incidence around 0.1%). In around 60% of cases, Barrett's oesophagus is associated with chronic gastro-oesophageal reflux, which is a major risk factor<sup>3</sup>. Barrett's oesophagus is found in 15-20% of adults undergoing endoscopic investigation of symptomatic chronic reflux. The condition can, however, develop in the absence of symptoms and only 5-10% of adults with reflux develop Barrett's oesophagus<sup>4</sup>. Other factors associated with increased risk of developing Barrett's oesophagus are Caucasian race, male sex, and older  $age^{2,5}$ .

Men with Barrett's oesophagus have an absolute lifetime risk of developing oesophageal adenocarcinoma of about 5% compared with 3% for women<sup>4</sup>. In studies of patients with Barrett's oesophagus with HGD undergoing surveillance, approximately six patients per 100 patient-years develop oesophageal adenocarcinoma. The combined incidence of HGD and oesophageal adenocarcinoma in patients under surveillance is estimated to be higher in the UK (13.0/1,000 patient-years; 95% CI 7.4 to 22.8) than in other European countries (7.3/1,000 patient-years; 95% CI 3.6 to 15.0)<sup>6</sup>.

<sup>&</sup>lt;sup>2</sup> Jankowski JA. Barrett esophagus and surveillance in the United Kingdom. Gastroenterol Hepatol. 2009;5(11):766-8

<sup>&</sup>lt;sup>3</sup> Jankowski J, Barr H, Wang K, Delaney B. Diagnosis and management of Barrett's oesophagus. BMJ. 2010;341:c4551

<sup>&</sup>lt;sup>4</sup> Wild CP, Hardie LJ. Reflux, Barrett's oesophagus and adenocarcinoma: burning questions. Nat Rev Cancer. 2003;3(9):676-84

<sup>&</sup>lt;sup>5</sup> DynaMed. Barrett esophagus. Ipswich (MA): EBSCO Publishing; 2012.

<sup>&</sup>lt;sup>6</sup> Sikkema M, de Jonge PJ, Steyerberg EW, Kuipers EJ. Risk of esophageal adenocarcinoma and mortality in patients with Barrett's esophagus: a systematic review and meta-analysis. Clin Gastroenterol Hepatol. 2010;8(3):235-44

The rate of progression to cancer among patients with Barrett's oesophagus in the UK as a whole is approximately 1% per year<sup>7</sup>. The average risk of mortality attributable to oesophageal adenocarcinoma among Barrett's oesophagus patients under surveillance has been estimated at 0.3% per year (incidence 3.0/1,000 patient-years; 95% CI 2.2 to 3.9)<sup>5</sup>.

# **1.4 Current Treatment**

Removal of the Barrett's epithelium, prior to the development of cancer, is The traditional approach possible. has been surgical resection (oesophagectomy), a highly invasive procedure. Over the last decade endoscopic therapies including argon plasma coagulation (APC), photodynamic therapy (PDT), and endoscopic mucosal resection (EMR) have been developed. Each of these interventions, has been associated with specific benefits and risks to the patient.

# **1.5 Proposed Treatment**

More recently, clinical data has become available regarding the use of RFA as a more advanced technique for completely removing the Barrett's epithelium, with better outcomes and other benefits for patients (see section 3).

There is high level evidence to support the use of targeted EMR of persistent LGD, visible HGD and early mucosal cancer arising in Barrett's oesophagus followed by eradication of the Barrett's segment with RFA. This approach for HGD and early mucosal cancer is associated with reduced morbidity and mortality compared with surgical treatment and NICE have issued guidance to confirm that it is both a safe and effective treatment (Epithelial radiofrequency ablation for Barrett's oesophagus Interventional Procedures Guideline (IPG344] Published 26 May 2010 and Endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia Interventional Procedures Guideline (IPG496] Published 23 July 2014)

The evidence included in IPG344 and IPG496 suggests these procedures may be used in patients with Barret's Oesophagus with HGD and persistent LGD provided that normal arrangements are in place for clinical governance, consent, and audit.

# **1.6 What NHS Wales has decided**

WHSSC has carefully reviewed the evidence of RFA for the management of Barrett's Oesophagus in adults. We have concluded that there is enough evidence to fund the use of RFA, within the criteria set out in section 2.1.

<sup>&</sup>lt;sup>7</sup> Jankowski JA. Barrett esophagus and surveillance in the United Kingdom. Gastroenterol Hepatol. 2009;5(11):766-8

# **1.7** Relationship with other documents

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

# • NHS Wales

- All Wales Policy: <u>Making Decisions in Individual Patient Funding</u> <u>requests</u> (IPFR).
- NHS Wales Governance Manual: Patient Consent to Examination and Treatment <u>http://www.wales.nhs.uk/governance-emanual/patientconsent</u>

## • WHSSC policies and service specifications

 WHSSC service specification: CP183b, Radiofrequency Ablation (RFA) for the Management of Barrett's Oesophagus in Adults

# • National Institute of Health and Care Excellence (NICE) guidance

- Epithelial radiofrequency ablation for Barrett's oesophagus Interventional Procedures Guideline (IPG344] Published 26 May 2010 <u>https://www.nice.org.uk/guidance/ipg344</u>
- Barrett's oesophagus: ablative therapy Clinical Guideline [CG106] Published 11 August 2010 <u>https://www.nice.org.uk/Guidance/CG106</u>
- Endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia Interventional Procedures Guideline (IPG496] Published 23 July 2014 <u>https://www.nice.org.uk/guidance/ipg496</u>

## • Other published documents

- British Society of Gastroenterology/Fitzgerald RC, di Pietro M, Ragunath K, et al.: Guidelines on the diagnosis and management of Barrett's oesophagus Gut. 2014; 63(1): 7–42. <u>https://www.bsg.org.uk/resource/bsg-guidelines-on-the-diagnosis-and-management-of-barrett-s-oesophagus.html</u>
- Addendum to the British Society of Gastroenterology: Guidelines on the diagnosis and management of Barrett's oesophagus (2015) <u>https://www.bsg.org.uk/resource/bsg-guidelines-on-the-diagnosis-</u> <u>and-management-of-barrett-s-oesophagus.html</u>
- Revised British Society of Gastroenterology recommendation on the diagnosis and management of Barrett's oesophagus with low-grade dysplasia (2017) <u>https://www.bsg.org.uk/resource/bsg-guidelineson-the-diagnosis-and-management-of-barrett-s-oesophagus.html</u>

- Healthcare Quality Improvement Partnership: National Oesophago-Gastric Cancer Audit: Annual report 2018 <u>https://www.hqip.org.uk/resource/national-oesophago-gastric-</u> <u>cancer-audit-annual-report-2018</u>
- Welsh Association for Gastroenterology and Endoscopy: Clinical Technical guidance for implementation & monitoring of compliance with National (BSG) guidelines on the diagnosis and management of Barrett's oesophagus (2014) https://www.wage.org.uk/

# 2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding of RFA for adults with Barrett's Oesophagus, in-line with the criteria identified in the policy.

#### 2.1 Inclusion Criteria

Patient selection for endoscopic radiofrequency ablation for Barrett's oesophagus with high-grade dysplasia or low-grade dysplasia should be agreed by a multidisciplinary team (MDT) experienced in managing Barrett's oesophagus, as described in the British Society of Gastroenterology guidelines. This will be the regional Upper Gastrointestinal (Upper GI) MDT.

Radiofrequency ablation will be commissioned for adults aged 18 years with a confirmed diagnosis of Barrett's Oesophagus with either of the following:

- Intramucosal carcinoma, or
- High Grade Dysplasia (HGD), or
- Persistent Low Grade Dysplasia (LGD)

#### Barrett's oesophagus

Barrett's oesophagus is diagnosed if any portion of the normal distal squamous epithelial lining of the oesophagus has been replaced by metaplastic columnar epithelium. This should be clearly visible endoscopically ( $\geq 1$  cm) above the gastro-oesophageal junction (GOJ) and confirmed histopathologically from oesophageal biopsies.<sup>8</sup>

#### Intramucosal carcinoma

A lesion in which neoplastic cells have penetrated the basement membrane and invaded the lamina propria or muscularis mucosae, but without invasion into the submucosa.

#### High Grade Dysplasia

Dysplasia can be either flat or have a polypoid appearance. The distinction between HGD and LGD is largely based on the presence of architectural changes in conjunction with more marked nuclear atypia. Commonly agreed definitions of low and high-grade dysplasia are not available, and are often unhelpful. HGD should be confirmed and graded by an experienced histopathologist based on the architectural and cytological appearance of the abnormal area. Dysplasia should be 'double-reported',

<sup>&</sup>lt;sup>8</sup> This definition and the definitions below are taken from the British Society of Gastroenterology/Fitzgerald RC, di Pietro M, Ragunath K, et al.: Guidelines on the diagnosis and management of Barrett's oesophagus Gut. 2014; 63(1): 7–42. <u>https://www.bsg.org.uk/resource/bsg-guidelines-on-the-diagnosis-and-management-of-barrett-s-oesophagus.html</u>

Welsh Health Specialised Services Committee (WHSSC) April 2020

i.e. confirmed by a second pathologist with an interest in upper gastrointestinal pathology.

## Persistent Low Grade Dysplasia

Persistent LGD should be confirmed as being present on two separate occasions by two experienced upper GI histopathologists.

## 2.2 Exclusion Criteria

This policy excludes people with Barrett's oesophagus and:

- with intestinal metaplasia (IM) alone, i.e. without dysplasia
- indefinite for dysplasia
- non-persistent LGD (i.e. present on one occasion only)

#### Indefinite for dysplasia

This is used to describe cases where the morphological features between true dysplasia and regenerative/ inflammatory atypia are blurred.

It is important to appreciate that this diagnosis could mean that people with Barrett's Oesophagus may have features suspicious of HGD, but there is not enough certainty present to warrant diagnosis.

The uncertainty precluding a confident diagnosis of dysplasia may be due to technical factors, such as:

- poor staining
- poor orientation
- cross cutting or denuded surface epithelium
- severe active inflammation
- ulceration leading to marked atypia.

In other cases, the epithelium appears abnormal, but the features are not sufficiently well developed to justify a definite diagnosis of dysplasia.

Evidence of 'surface maturation' which loss of the cytological atypia seen in the deeper glands as the mucosa matures into the surface epithelium—is often taken as the best marker to favour regeneration rather than dysplasia, although this is also not invariably true.

Explicit mention in the pathology report of the reason justifying this diagnosis can be useful to aid management of the condition.

## 2.3 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.

# 2.4 Patient Pathway (Annex i)

Patient selection for endoscopic radiofrequency ablation for Barrett's oesophagus with high-grade dysplasia or low-grade dysplasia should be done by a multidisciplinary team experienced in managing Barrett's oesophagus, as described in the British Society of Gastroenterology guidelines. This will be the regional Upper GI MDT.

Referral to the endoscopic resection (ER)/RFA treatment centre for further assessment for suitability for endoscopic treatment.

If the patient is assessed as suitable for ER/RFA, s/he is listed for treatment.

Patients typically require an average of 3 sessions of RFA treatment over a 12 month period to successfully treat the affected area.

Following the conclusion of treatment, the patient is referred back to their local Upper GI service for on-going monitoring and surveillance.

#### 2.5 Designated Centre(s)

For people in North Wales:

Royal Liverpool University Hospital Prescot Street Liverpool L7 8XP

For people in South Wales:

University Hospital of Wales Heath Park Way Cardiff CF14 4XW

#### 2.6 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, and IPFR should be submitted.

Further information on making IPFR requests can be found at: <u>Welsh Health</u> <u>Specialised Services Committee (WHSSC) | Individual Patient Funding</u> <u>Requests</u> Commissioning Policy CP183a, Radiofrequency Ablation (RFA) for the Management of Barrett's Oesophagus

### 2.7 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties.

#### 2.8 Responsibilities

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinicians considering treatment should:

- discuss all the alternative treatment with the patient
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

# 3. Evidence

WHSSC is committed to regularly reviewing and updating all of its commissioning policies based upon the best available evidence of both clinical and cost effectiveness. A summary of the evidence to support the inclusion criteria in this policy is provided below.

# Low grade dysplasia (LGD)

The 2015 addendum to the British Society of Gastroenterology (BSG) guideline on the diagnosis and management of Barrett's oesophagus concluded that the management of LGD was unclear in view of limited data about the natural history. As a result the BSG were unable to routinely recommend ablation therapy at that time. However a further addendum to the BSG guideline published in 2017 included data from a multicentre RCT comparing the outcome of 68 patients with LGD treated with RFA with an equal number of patients undergoing annual endoscopic surveillance. Over a 3-year follow-up period, 1% of patients in the treatment arm progressed to HGD or cancer, compared with 26.5% in the control arm (p<0.001). This led to the BSG to recommend that patients with LGD should be offered endoscopic ablation therapy, preferably with RFA, after review by the specialist MDT.

In their 2018 surveillance report of CG106<sup>9</sup> NICE reported that the evidence base for endoscopic therapy in LGD remains limited, and consists of small RCTs and systematic reviews of mainly observational studies. Despite the limitations of the evidence base, evidence consistently shows that treating LGD is associated with reduced progression to HGD or cancer. One study suggests that this could be a reduction in progression from 13% to less than  $2\%^{10}$ .

NICE concluded that an update to CG106 was necessary to address the treatment of low-grade dysplasia and plan to commission this work in the autumn of 2019, with a likely publication date of September 2020.

# High grade dysplasia (HGD)

The BSG guideline<sup>11</sup> recommends that in the presence of HGD or intramucosal cancer without visible lesions (flat HGD/intramucosal cancer) patients should be managed with an endoscopic ablative technique. It reports that there are little comparative data among ablative techniques, but RFA currently has a better safety and side-effect profile and comparable efficacy.

<sup>10</sup> Qumseya BJ, Wani S, Gendy S, Harnke B, Bergman JJ, Wolfsen H (2017) Disease Progression in Barrett's Low-Grade Dysplasia With Radiofrequency Ablation Compared With Surveillance: Systematic Review and Meta-Analysis. American Journal of Gastroenterology 112(6):849–65 <sup>11</sup> <u>https://www.bsg.org.uk/resource/bsg-guidelines-on-the-diagnosis-and-management-of-barretts-oesophagus.html</u>

<sup>&</sup>lt;sup>9</sup> <u>https://www.nice.org.uk/guidance/cg106/evidence/appendix-a-summary-of-evidence-from-surveillance-pdf-6599631134</u>

The current NICE clinical guideline on Barrett's oesophagus: ablative therapy (CG106)<sup>12</sup> also makes recommendations for the use of RFA either alone or in combination with endoscopic resection.

#### RFA alone

RFA is recommended by NICE<sup>11</sup> as an option for the treatment of Barrett's oesophagus with flat high-grade dysplasia. This was based on a single highquality RCT<sup>13</sup> with a follow-up of 12 months that studied RFA alone (n = 42) compared with a sham procedure (n = 21). The study showed 81% eradication of dysplasia for the radiofrequency ablation arm compared with 19% in the sham arm (RR = 4.25, 95% CI 1.98 to 10.66). The progression of dysplasia to cancer was 2% in the radiofrequency ablation arm versus 18% in the sham arm (RR = 0.125; 95% CI 0.19–0.78). And based on a cost utility analysis, NICE also concluded that RFA was a cost-effective use of resources.

As part of their 2018 surveillance review of CG106<sup>14</sup> NICE have reported that new evidence on the effectiveness of RFA published since 2010 is consistent with their current recommendations.

#### Endoscopic mucosal resection in combination with RFA

As well as recommending endoscopic resection and ablative therapies separately, NICE also included them in combination as a possible treatment option<sup>11</sup>. They considered that there was sufficient evidence to support the additional use of ablative therapies (argon plasma coagulation, radiofrequency ablation and photodynamic therapy) after endoscopic mucosal resection for the treatment of high-grade dysplastic Barrett's oesophagus or early adenocarcinoma. NICE also concluded that that endoscopic mucosal resection plus an ablative therapy represented a cost-effective use of resources, whilst acknowledging that the estimates were based on very poor data.

More recent evidence published since 2010<sup>13</sup> suggests that endoscopic resection followed by radiofrequency ablation may be more effective than radiofrequency ablation alone, although adverse events may be more common.

<sup>&</sup>lt;sup>12</sup> <u>https://www.nice.org.uk/Guidance/CG106</u>

 <sup>&</sup>lt;sup>13</sup> Shaheen NJ, Sharma P, Overholt BF et al. (2009) Radiofrequency ablation in Barrett's esophagus with dysplasia. New England Journal of Medicine 360: 2277–88
<sup>14</sup> <u>https://www.nice.org.uk/quidance/cq106/evidence/appendix-a-summary-of-evidence-from-</u>

surveillance-pdf-6599631134

Commissioning Policy CP183a, Radiofrequency Ablation (RFA) for the Management of Barrett's Oesophagus

#### 3.1 Date of Review

This document is scheduled for review before 2023, where we will check if any new evidence is available. If no new evidence or intervention is available the review date will be progressed.

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

# 4. 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 reassignment, 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.

# 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 <u>NHS Putting Things Right</u>. For services provided outside NHS Wales the patient or their representative should be guided to the <u>NHS Trust</u> <u>Concerns Procedure</u>, with a copy of the concern being sent to WHSSC.

## 5.2 Individual Patient Funding Request (IPFR)

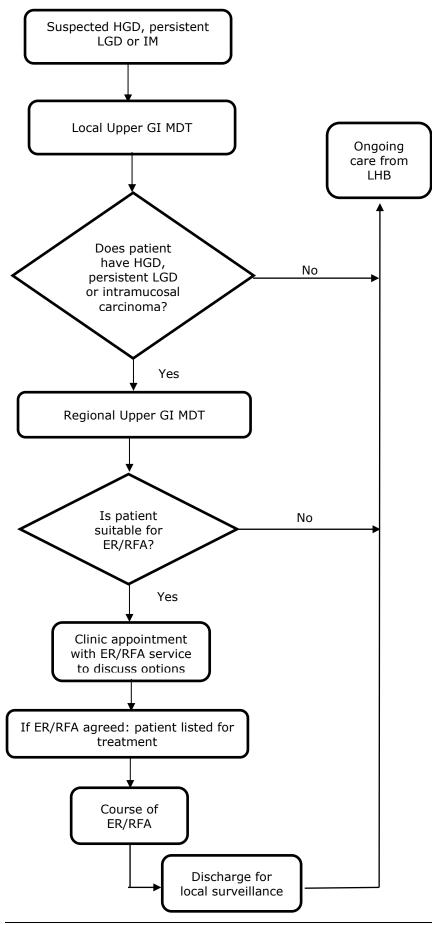
If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All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

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

# Annex i Patient Pathway



# Annex ii Checklist

#### Radiofrequency Ablation (RFA) for the Management of Barrett's Oesophagus

The following checklist should be completed for every patient to whom the policy applies:

- Where the patient meets the criteria **and** the procedure is included in the contract **and** the referral is received by an agreed centre, the form should be completed and retained by the receiving centre for audit purposes.
- The patient meets the criteria **and** is received at an agreed centre, but the procedure is not included in the contract, the checklist must be completed and submitted to WHSSC for prior approval to treatment.
- The patient meets the criteria but wishes to be referred to a noncontracted provider, an Individual Patient Funding Request (IPFR) Form must be completed and submitted to WHSSC for consideration.
- 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.

# Annex iii Codes

| Code Category | Code  | Description  |
|---------------|-------|--|
| OPCS          | G14.5 | Fibre optic endoscopic destruction of lesion of oesophagus NEC                   |
|               | Y13.4 | Radiofrequency controlled thermal destruction of lesion of organ NOC             |
|               | G43.5 | Fibre optic endoscopic destruction of lesion of upper gastrointestinal tract NEC |
|               | G14.3 | Fibre optic endoscopic cauterisation of lesion of oesophagus                     |
|               | Z27.1 | Oesophagus   |

# Annex iv Abbreviations and Glossary

# Abbreviations

| AWMSG | All Wales Medicines Strategy Group |
|-------|------------------------------------|
| IPFR  | Individual Patient Funding Request |
| SMC   | Scottish Medicines Consortium      |
| WHSSC | Welsh Health Specialised Services  |

#### 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.