GIG CYMRU NHS WALES

Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)

Welsh Health Specialised Services Committee (WHSSC)

Specialised Services
Policy Position Statement PP265

Teduglutide for treating Short Bowel Syndrome

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Document information	
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Commissioning Team	Neurosciences and Long-term Conditions
Target audience	**For information** Chief Executives, Medical Directors, Directors of Finance, Directors of Planning
	For action Chief Pharmacists, Gastroenterology Clinical Leads, Specialist Gastroenterology nurses, Chief Pharmacists, Dieticians
Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy
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Disclaimer

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

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 position statement.

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1. Introduction

This Policy Position Statement has been developed for the planning and delivery of teduglutide for treating short bowel syndrome for people resident in Wales. This treatment will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

In creating this document, WHSSC has reviewed the relevant guidance issued by the National Institute of Health and Care Excellence (NICE)[1] and has concluded that teduglutide for treating short bowel syndrome should be made available.

Welsh Language

WHSSC 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 WHSSC 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

WHSSC 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 WHSSC commitment.

[1] Overview | Teduglutide for treating short bowel syndrome | Guidance | NICE

1.1 Background[1]

Short Bowel Syndrome

Short bowel syndrome (SBS) is a chronic and potentially life-threatening rare condition characterised by an inability to maintain protein-energy, fluid, electrolyte or micronutrient balances when on a normal diet. Some patients with intestinal insufficiency are able to adapt metabolically and compensate for their malabsorption by increasing oral or enteral intake. However other patients with intestinal failure depend on parenteral support which is associated with serious complications (including infections and liver damage) and has a negative impact of quality of life.

SBS is commonly caused by surgery that has been needed to remove abnormal bowel. In adults, this surgery may be needed for a range of conditions, including mesenteric ischaemia, Crohn's disease and radiation enteritis. In children, it is often because of necrotising enterocolitis in premature babies, or other conditions such as volvulus or gastroschisis. Some children can be born with a short bowel. SBS can lead to intestinal failure. This is when the length of intestine remaining means the intestinal functions drops below the necessary level for absorption of nutrients, water and electrolytes. Intestinal failure is classified as type 3 when it is chronic and people need to have parenteral support over months or years.

Epidemiology

SBS affects males and females in equal numbers. The disorder is usually acquired during life, but in rare cases may be present at birth (congenital). The exact incidence and prevalence of short bowel syndrome in the general population is unknown[2].

Current Treatment

Current treatment for SBS includes parenteral support, in which nutrients and fluids are given intravenously for an average of 10 to 14 hours a day for between 2 and 7 days a week. Most people have parenteral support at home using a permanent intravenous tube. While parenteral support is life-saving, it is very time-consuming, highly complex and its complications can be life threatening. These include blood infections, blood clots, and kidney and liver failure. Intestinal transplantation may be an alternative treatment option for selected patients when other treatments have failed.

Teduglutide (Revestive®)

Teduglutide is a glucagon-like peptide-2 (GLP-2) analogue which has been shown to preserve mucosal integrity by promoting repair and normal growth of the intestine through an increase of villus height and crypt depth. Teduglutide has marketing authorisation for the treatment of patients with

[2] Short Bowel Syndrome - NORD (National Organization for Rare Disorders) (rarediseases.org)

SBS who are aged at least one year and are stable following a period of intestinal adaptation after surgery[3,4,5]. Stability should be at least 6 months in adults; and 3 months for children.

1.2 Equality Impact 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 WHSSC 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 subject to an Equality Impact Assessment in line with guidance contained in CPL-026[6].

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.

An EQIA was also carried out by NICE during the evaluation of Teduglutide for treating acute hepatic porphyria. For further details, please refer to the NICE website at: Overview | Teduglutide for treating short bowel syndrome | Guidance | NICE

[3] Revestive 1.25 mg powder and solvent for solution for injection - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)
[4] Revestive 5 mg powder and solvent for solution for injection - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)
[5] Revestive | European Medicines Agency (europa.eu)
[6] https://whssc.nhs.wales/publications/corporate-policies-and-procedures/corp-026-eqia-policy/

2. Recommendations

The recommendations below represent the views of NICE, arrived at after careful consideration of the evidence available. Health professionals are expected to take into account the relevant NICE guidance[7], alongside the individual needs, preferences and values of the patient.

2.1 Inclusion Criteria

- Teduglutide is recommended, within its marketing authorisation, as an option for treating short bowel syndrome (SBS) in people 1 year and above.
- People's condition should be stable following a period of intestinal adaptation after surgery before having teduglutide*.
- Teduglutide is recommended only if the company provides it according to the commercial arrangement[7].
- The patient requires parenteral support at least 3 times weekly[8] and has had a stable parenteral support volume for at least 4 weeks prior to dosing.

*Treatment should not be initiated until it is reasonable to assume that a patient is stable following a period of intestinal adaptation. Stability should be at least 6 months in adults; and 3 months for children. Optimisation and stabilisation of intravenous fluid and nutrition support should be performed before initiation of treatment.

Treatment should be initiated under the supervision of a medical professional with experience in the treatment of SBS.

2.2 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given. Providers are expected to develop a long-term surveillance protocol to routinely assess patients being treated with tedglutide.

There is a minimum requirement to review all patients commenced on tedglutide at six months and twelve months respectively.

[7] Overview | Teduglutide for treating short bowel syndrome | Guidance | NICE

[8] This criteria is in line with the eligibility criteria for participants in the pivotal study trials STEPS (Jeppesen P, Pertkiewicz M, Messing B, Iyer K, Seidner D, O'Keefe S, et al. Teduglutide reduces need for parenteral support among patients with short bowel syndrome with intestinal failure. Gastroenterology. 2012;143(6):1473-81) and 004 (Jeppesen PB, Gilroy R, Pertkiewicz M, Allard JP, Messing B, O'Keefe SJ. Randomised placebo-controlled trial of teduglutide in reducing parenteral nutrition and/or intravenous fluid requirements in patients with short bowel syndrome. Gut. 2011;60(7):902-14).

2.3 Stopping Criteria

It is recommended that adults should have an evaluation after 6 months, with treatment continuation being reconsidered if there is no treatment benefit by 12 months.

Treatment benefit is classed as a reduction of at least 1 day of parenteral support per week at 12 months compared with baseline, or by achieving at least a 20% reduction in fluid or calories in parenteral support requirements[9].

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 Designated Providers

Adult service

University Hospital of Wales
Gastroenterology Department (Adult service)
Heath Park,
Cardiff
CF14 4XW

Salford Royal NHS Foundation Trust
Gastroenterology Department
Stott Ln,
Salford
M6 8HD

Children's service

University Hospital of Wales
Gastroenterology Department (children's service)
Heath Park,
Cardiff
CF14 4XW

[9] https://www.nice.org.uk/guidance/ta804

Alder Hey Children's Hospital
Gastroenterology Department
E Prescot Rd,
Liverpool
L14 5AB

2.6 Blueteq and reimbursement

Teduglutide will only be funded for patients registered via the Blueteq system and where an appropriately constructed MDT has approved its use within a specialised treatment centre.

Where the patient meet the criteria in this policy and the referral is received by an agreed centre, a Blueteq form should be completed for approval. For further information on accessing and completing the Blueteq form please contact WHSSC using the following e-mail address: WHSSC.blueteq@wales.nhs.uk

If a non-contracted provider wishes to treat a patient that meets the criteria they should contact WHSSC (e-mail: WHSSC.IPC@Wales.nhs.uk). They will be asked to demonstrate they have an appropriate MDT in place.

Teduglutide has a marketing authorisation in the UK for 'the treatment of patients aged 1 year and above with SBS. Patients should be stable following a period of intestinal adaption after surgery'. It is administered by subcutaneous injection. The dosage schedule is available in the summary of product characteristics for teduglutide[10].

The list price of a 5mg vial of teduglutide is £521.98 and the 1.25mg vial of teduglutide is £260.99 (excluding VAT; BNF online, accessed December 2022[11]). The company has a commercial arrangement. This makes teduglutide available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

2.7 Action to be taken

- Health Boards and WHSSC are to circulate this Policy Position Statement to all Hospitals/MDTs to inform them of the conditions under which the technology will be commissioned.
- WHSSC are to ensure that all providers are purchasing teduglutide at the agreed discounted price.
- Providers are to ensure that all providers understand the need to approve teduglutide at the appropriate MDT and are registering use

[10] Revestive 5 mg powder and solvent for solution for injection - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)
[11] Medicinal forms | Teduglutide | Drugs | BNF | NICE

on the Blueteq system, and the treatment will only be funded where the Blueteq minimum dataset is fully and accurately populated.

- Providers should ensure that the required data will be submitted to the Intestinal Failure Registry.
- Providers are to determine estimated patient numbers and the current dose of any patient(s) who will transfer from any company compassionate use scheme or EAMS where applicable.
- The Provider should work to written quality standards and provide monitoring information to WHSSC on request.

3. Putting Things Right

3.1 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.

3.2 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 All Wales IPFR Panel will then consider the request.

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